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<p>(21) International Application Number: PCT/US98/19634</p> <p>(22) International Filing Date: 18 September 1998 (18.09.98)</p> <p>(30) Priority Data: 60/061,134 6 October 1997 (06.10.97) US</p> <p>(71) Applicant (for all designated States except US): UNITED STATES SURGICAL CORPORATION [US/US]; 150 Glover Avenue, Norwalk, CT 06850-1308 (US).</p> <p>(71)(72) Applicants and Inventors: EHRENFELS, Karl, H. [US/US]; 583 Danbury Road, Ridgefield, CT 06877 (US). LEE, Daniel, R. [US/US]; 15 Devonshire Lane, Madison, CT 06443 (US). MILLER, Eric [US/US]; 30 Sleepy Hollow Road, Fairfield, CT 06430 (US). YOGAMI, Richard [US/US]; 4 Cottonwood Lane, Ridgefield, CT 06877 (US). RETHY, Csaba, L. [US/US]; 303 Pansy Road, Fairfield, CT 06430 (US).</p> <p>(74) Agents: LIKOUREZOS, George et al.; Dilworth & Barrese, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>
<p>(54) Title: FIBRIN SEALANT APPLICATOR</p> <div data-bbox="548 1136 1062 1570" data-label="Image"> </div> <p>(57) Abstract</p> <p>A fibrin sealant spray gun applicator and a cartridge assembly are provided for dispensing a first, and a second protein solution to form a biological adhesive. The first and second protein solutions are preferably fibrinogen, and thrombin solutions which intermix on an application site to form a fibrin sealant. The cartridge assembly includes two piston type subassemblies (12) each having a plunger (16), and a cylindrical container (14). Each container stores one of the two solutions therein, and has a nozzle at a distal end for dispensing the solutions as an actuator of the cartridge assembly is moved distally to create positive pressure within the containers. The solutions are dispensed in a drip-like manner for the adhesive to cover a limited area. A drip applicator (34) can be mating mounted to both container nozzles for externally intermixing the solutions before being dripped onto the application site. The fibrin sealant spray gun applicator includes a housing (52) having an elongated body portion (54) defining a longitudinal axis, and a stationary handle projecting from elongated body portion. The spray gun applicator further includes a drive member assembly having a movable trigger handle pivotally connected to the housing adjacent the stationary handle to form a pistol type grip (58).</p>		

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FIBRIN SEALANT APPLICATOR

PRIORITY

This application claims priority to a U.S. Provisional Application Serial No.
5 60/061,134 filed on October 6, 1997.

BACKGROUND

1. Technical Field

The disclosure relates generally to an applicator for applying a tissue
sealant based on human or animal proteins and more particularly to an apparatus for
10 applying an adhesive formed by combining solutions of the proteins to tissues or
organs for sealing wounds or leaks, stopping bleeding and the like.

2. Description of Related Art

A fibrin sealant is a biological adhesive sealant formed by mixing two
protein components, including fibrinogen and thrombin. Each protein component is
15 derived from human plasma and is subjected to virus elimination and/or inactivation
procedures. The components are typically individually dehydrated and stored in
separate vials as sterile freeze-dried powders.

It is known that purified fibrinogen and thrombin, together with a
variety of known adjuvants, can be combined in vitro to produce a hemostatic agent
20 and/or a tissue sealant. Because of the rapid interaction of fibrinogen and thrombin,
it is important to maintain these two blood proteins separate until applied at the
application site. These protein solutions are generally delivered by devices such as a
dual syringe apparatus.

One dual syringe apparatus for applying a fibrinogen-based tissue
25 adhesive is disclosed in U.S. Pat. No. 4,359,049 to Redl et al. Redl et al. disclose a
mechanism in which two standardized one-way syringes are held in a support having a

common actuating means. The dispensing end of each syringe is inserted into a collection manifold where the two components are mixed. The components are then dispensed through a common needle capable of covering a limited area of the application site.

5 However, it is sometimes desirable or necessary to cover a broad area of a wound, either to stop bleeding, to fix tissue or to prevent infection and sometimes it is desirable to cover a limited area. It is also desirable to prevent the two components from mixing within the dispensing device.

10 Additionally, a dual syringe apparatus for the application of fibrinogen and thrombin solutions to an application site generally contains several parts, such as a syringe plunger, a "Y" manifold connector, a dispensing needle, a syringe holder, syringe needles, and conduits for transporting the solutions to the dispensing needle. Therefore, known fibrin sealant applicators, such as disclosed in U.S. Patent to Redl et al. discussed above, and in U.S. Patent Nos. 4,874,368 to Miller et al. and
15 4,979,942 to Wolf et al. are difficult to reuse. The replenishment of the protein components typically require a combination of steps including, *inter alia*, removing a clip which couples the syringe plunger, removing the syringe plunger, detaching the syringes from the "Y" connector, removing the syringes from the holder, inserting new syringes, affixing the syringes to the "Y" connector, adding fibrinogen to one
20 syringe and thrombin to another syringe, replacing the syringe plunger, replacing the plunger clip, and dispensing the solutions. In an application where time is of the essence, such a lengthy replenishing process is impractical and cumbersome.

25 Thus, there is a need in the art for a fibrin sealant applicator wherein the adhesive can cover a broad or a limited area of a wound, either to stop bleeding, seal leaks, to fix tissue or to prevent infection. There is also a need for a fibrin sealant applicator wherein a manual force is applied via an activator assembly having a mechanism for preventing air from entering reservoirs containing the solutions.

Further, there is a need for a fibrin sealant applicator wherein the adhesive components are not susceptible to contamination and the adhesive components are not undesirably intermixed within the applicator.

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In addition, there is a need for a fibrin sealant applicator wherein the component solutions are easily replenished. There is also a need for a fibrin sealant applicator which is self-cleaning and reusable with different component solutions. Further, there is a need for a fibrin sealant applicator which is inexpensive to manufacture for allowing the applicator to be disposed of after use.

SUMMARY

A fibrin sealant spray gun applicator and a cartridge assembly are provided for dispensing a first and a second protein solution to form a biological adhesive. The first and second protein solutions are preferably fibrinogen and thrombin solutions which intermix on an application site to form a fibrin sealant. In a preferred embodiment the cartridge assembly includes two piston-type sub-assemblies, each having a plunger and a cylindrical container. Each container stores one of the two solutions therein and includes an opening at a distal end for dispensing the solutions as a connector head connecting the two containers is moved distally to create positive pressure within the containers. The solutions are dispensed within pathways in the plungers. The pathways are in fluid communication with respective nozzles at the distal end of the cartridge assembly to dispense the solutions in a drip-like manner for the adhesive to cover a limited area. A drip applicator can be matingly mounted to the nozzles for externally intermixing the solutions before being dripped onto the application site.

The fibrin sealant spray gun applicator includes a housing having an elongated body portion defining a longitudinal axis and a stationary handle projecting from elongated body portion. The spray gun applicator further includes a drive member assembly having a movable trigger handle pivotally connected to the housing adjacent the stationary handle to form a pistol-type grip. The cartridge assembly is removably mounted within the elongated body portion such that the cartridge assembly nozzles are in fluid communication via respective channels with a corresponding nozzle at the distal end of the elongated body portion. As the trigger handle is depressed, the cartridge connector head is moved distally thereby creating positive pressure within the containers to cause the solutions therein to be dispensed

via the spray gun nozzles in a spray-like manner for the adhesive to cover a broad area.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of a cartridge assembly for housing protein solutions which form a biological adhesive when intermixed;

FIG. 2 is a cross-sectional view of the cartridge assembly of FIG. 1;

FIG. 3 is a perspective view of the cartridge assembly of FIG. 1 dispensing the protein solutions in a drip-like manner;

FIG. 3A is a cross-sectional view of the cartridge assembly of FIG. 1 dispensing the protein solutions;

FIG. 4 is a perspective view of a drip applicator;

FIG. 5 is a cross-sectional view of the drip applicator of FIG. 4;

FIG. 5A is a perspective view of an alternative embodiment of the drip applicator having a substantially flat side for spreading and mixing the protein solutions;

FIG. 6 is a perspective view of the drip applicator of FIG. 5 matingly mounted to the cartridge assembly of the embodiment of FIG. 1;

FIG. 6A is a perspective view of the drip applicator of FIG. 5 matingly mounted to an alternative embodiment of the cartridge assembly;

FIG. 7 is a perspective view of the cartridge assembly of FIG. 1 having the drip applicator mounted thereon dispensing the protein solutions in a drip-like manner;

FIG. 7A is a perspective view of the cartridge assembly of FIG. 6A having the drip applicator mounted thereon dispensing the protein solutions in a drip-like manner;

FIG. 8 is a perspective view of a preferred embodiment of a fibrin sealant spray gun applicator;

FIG. 8A is a cross-sectional view of the fibrin sealant spray gun applicator taken along line 8A-8A in FIG. 8;

FIG. 8B is a cross-sectional view of an alternate fibrin sealant spray gun having a safety interlock mechanism;

FIG. 9 is a cross-sectional view of a distal end of the fibrin sealant spray gun applicator of FIG. 8;

FIG. 10 is a top view of the fibrin sealant spray gun applicator of the embodiment of FIG. 8;

FIG. 10A is a perspective view of the fibrin sealant spray gun applicator of the embodiment of FIG. 8;

FIG. 11 illustrates the cartridge assembly of the embodiment of FIG. 1 being mounted to the fibrin sealant spray gun applicator of the embodiment of FIG. 8;

FIG. 12 is a perspective view of the cartridge assembly of the embodiment of FIG. 1 mounted to the fibrin sealant spray gun applicator of the embodiment of FIG. 8;

FIG. 13 is a top view of the cartridge assembly of the embodiment of FIG. 1 mounted to the fibrin sealant spray gun applicator of the embodiment of FIG. 8;

FIG. 14 is a perspective view of the fibrin sealant spray gun applicator of the embodiment of FIG. 8 with the movable trigger fully depressed to dispense the

protein solutions in a spray-like manner;

FIG. 14A is a cross-sectional view of the fibrin sealant spray gun applicator taken along line 14A-14A in FIG. 14;

FIG. 14B is an enlarged cross-sectional view of the trigger mechanism;

5 FIG. 15 is a perspective view of a third embodiment of the cartridge assembly having a drip conversion accessory pivotable between a drip position for dispensing the solutions in a drip-like manner and a non-drip position;

FIG. 16 is a perspective view of the cartridge assembly of the embodiment of FIG. 15 with the drip conversion accessory pivoted to the a non-drip position;

10 FIG. 16A is an assembly view of the drip conversion accessory with the cartridge assembly shown in FIG. 15;

FIG. 17 is a cross-sectional view of the drip conversion accessory;

15 FIG. 18 is a cross-sectional view of the drip conversion accessory taken along line 18-18 in FIG. 17;

FIG. 19 is a cross-sectional view of the cartridge assembly of FIG. 15 taken along line 19-19 in FIG. 15;

FIG. 20 is a cross-sectional view taken along line 20-20 of FIG. 19;

20 FIG. 21 is a cross-sectional view of the cartridge assembly of FIG. 15 dispensing the solutions in a drip-like manner;

FIG. 22 is a perspective view of the cartridge assembly of FIG. 15 dispensing the solutions in a drip-like manner;

FIG. 23 is a cross-sectional side view of the cartridge assembly of FIG. 15 with the drip conversion accessory in the non-drip position;

25 FIG. 24 is a perspective view of a second embodiment of the fibrin

sealant spray gun applicator showing the cartridge assembly of the embodiment of FIG. 15 being mounted therein;

FIG. 25 is a perspective view of the fibrin sealant spray gun applicator of the embodiment of FIG. 24 dispensing the solutions in a spray-like manner;

5 FIG. 26 is a perspective view of a coupler unit mounted onto the cartridge assembly of the embodiment of FIG. 1 for loading the solutions within the cartridge assembly;

FIG. 26A is a perspective view of the cartridge assembly of FIG. 1 being coupled to coupler unit shown in FIG. 26;

10 FIG. 26B is a perspective view of a first alternative coupler unit having a drawer assembly for placement of the vials;

FIG. 26C is a perspective view of the drawer assembly of the coupler unit shown in FIG. 26B;

15 FIG. 26D is a perspective view of a second alternative coupler unit having a flip-top housing for placement of the vials therein;

FIG. 26E is a perspective view of a needle assembly of the coupler unit shown in FIG. 26D;

FIG. 27 is a cross-sectional view of the cartridge assembly of the embodiment of FIG. 1 with the coupler unit of FIG. 26 mounted thereon;

20 FIG. 27A is a cross-sectional view of the cartridge assembly-coupler unit showing the cartridge assembly filled;

FIG. 28 is a perspective view of a fourth embodiment of a cartridge assembly for dispensing protein solutions in a drip-like manner;

25 FIG. 29 is a perspective view of a fifth embodiment of a cartridge assembly for dispensing protein solutions in a drip-like manner;

FIG. 30 is a perspective view of a first alternative embodiment for the conically-shaped distal end of the fibrin spray gun applicator shown in FIG. 8;

FIG. 31 is a cross-sectional view of the distal end of the fibrin spray gun applicator taken along line 31-31 in FIG. 30;

5 FIG. 32 is a side view of a second alternative embodiment for the conically-shaped distal end of the fibrin spray gun applicator shown in FIG. 8;

FIG. 33 is a cross-sectional view of the distal end of the fibrin spray gun applicator taken along line 33-33 in FIG. 32;

10 FIG. 34 is a side view showing a portion of the distal end of the fibrin spray gun applicator shown in FIG. 32 moveable from an atomized mist position to a stream position;

FIG. 34A is a side view showing another portion of the distal end of the fibrin gun applicator being pivotable for ease of cartridge insertion and removal;

15 FIG. 34B is a side view of an alternate embodiment of the fibrin sealant applicator having a pivotable distal end for ease of cartridge insertion and removal;

FIG. 35 is a front view of a first embodiment of the distal end of a dripper tip cannula assembly for connection to the cartridge assembly of FIG. 1;

20 FIG. 35A is a cross-sectional view taken along line 35A-35A in FIG. 35;

FIG. 36 is a front view of a second embodiment of the distal end of a dripper tip cannula assembly for connection to the cartridge assembly of FIG. 1;

FIG. 36A is a cross-sectional view taken along line 36A-36A in FIG. 36;

25 FIG. 37 is a front view of a third embodiment of the distal end of a

dripper tip cannula assembly for connection to the cartridge assembly of FIG. 1;

FIG. 37A is a cross-sectional view taken along line 37A-37A in FIG. 37;

FIG. 38 is a perspective view of a dripper assembly having a cartridge assembly mounting configuration for insertion of the cartridge assembly of FIG. 1
5 therein;

FIG. 39 is a perspective view of the dripper assembly having the cartridge assembly of FIG. 1 mounted within the cartridge assembly mounting configuration;

FIG. 40 is a cross-sectional view of a sprayer assembly having a cartridge assembly mounting configuration for insertion of the cartridge assembly of FIG. 1
10 therein;

FIG. 41 is an enlarged cross-sectional view of the distal end of the sprayer assembly shown by FIG. 40;

FIG. 42 is a perspective view of a dripper assembly having an unclogging system;

FIG. 43 is a cross-sectional view of the dripper assembly of FIG. 42 with the unclogging system in the clogging position;

FIG. 44 is a cross-sectional view of the dripper assembly of FIG. 42 with the unclogging system in the unclogging position; and

FIG. 45 is a cross-sectional view taken along line 45-45 in FIG. 44.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to FIG. 1-2, a fibrin sealant cartridge assembly according to a preferred embodiment of the present disclosure is shown. The assembly designated generally by numeral 10 includes two piston-type sub-assemblies 12 each having a container 14 and a plunger 16. The containers 14 are formed as a unitary housing unit 18 having a connector head 20 at a proximal end for stabilizing the containers 14. A stabilizing mount 21 at the distal end of the cartridge assembly 10 adjoins and stabilizes the plungers 16 and includes a "V"-shaped notch 23.

Each container stores one of two protein solutions therein which form a biological adhesive when intermixed. In the preferred embodiment, the biological protein solutions are a fibrinogen solution and a thrombin solution which intermix to form a fibrin sealant. It is to be understood, however, that other biological fluids may be substituted, depending upon the choice of mixture that is to be dispensed.

The connector head 20 aids in distally moving the containers 14 along the longitudinal axis of the cartridge assembly 10. As the unitary housing unit 18 is moved distally towards the plungers 16, positive pressure is created within the containers 14 as the amount of area for storing the solutions is decreased to dispense the solutions within pathways 32 (see FIG. 2) in the plungers 16. The pathways 32 in fluid communication with the nozzles 24 to dispense the solutions onto an application site in a drip-like manner as shown by FIGS. 3 and 3A.

It is contemplated to provide a ratchet mechanism in operative association with the connector head 20 to prevent the connector head 20 from moving proximally, thereby preventing air from entering the containers 14 and making it difficult to distally move the connector head 20 preventing unintentional dispensing of fluid. It is further contemplated to provide at least one lined extension on the inner

surface of the containers 14 and at least one matingly engaging track on the outer surface of the plungers 16 to have the containers 14 ride on the track as the connector head 20 is move distally.

After the solutions have been depleted from the containers 14, the solutions can be easily replenished by mounting a coupler unit 26 shown in FIGS. 26-27A to the cartridge assembly 10 and dispensing the protein solutions from vials 25 into containers 14 through aspirating needles 27. When the coupler unit 26 is mounted to the cartridge assembly 10, the cartridge assembly 10 cannot be used to dispense the solutions onto an application site. The cartridge assembly 10 is preferably manufactured from inexpensive materials allowing the assembly 10 to be disposed of after use. The assembly 10 can also be cleaned and reused with different component solutions. It is noted that the coupler unit 26 is designed to replenish the solutions for additional embodiments of the cartridge assembly, including cartridge assemblies 10A and 200, described below.

With reference to FIG. 4 a drip applicator designated by reference numeral 34 is shown for dispensing the solutions in closer proximity to one another. Drip applicator 34 is frustum-shaped and includes two proximal openings 36 and two distal openings 38. The proximal openings 36 are in respective fluid communication with the distal openings 38 through pathways 40 and 42, as shown by the cross-sectional view of FIG. 5. In addition, the drip applicator 34 is taller at the proximal end than the distal end to allow the solutions to flow towards the distal openings 38. An alternative embodiment of the drip applicator is shown by FIG. 5A and designated by reference numeral 34A. Drip applicator 34A includes a substantially flat spatula-shaped side 35A to allow a user to spread and/or further mix the protein solutions on the application site after they have been dispensed through distal openings 38A.

As shown by FIG. 6, the drip applicator 34 is connected to the cartridge assembly 10 by matingly engaging the proximal openings 36 with the nozzles 24. Upon distal movement of the connector head 20, each solution is dispensed from its corresponding nozzle 24 into one of the pathways 40 and 42 of the drip applicator 34. Each solution then flows through the pathways 40 and 42 and is dispensed from the cartridge assembly 10 from distal openings 38. The solutions intermix before being dripped onto the application site as shown by FIG. 7.

FIG. 6A shows an alternative embodiment for the cartridge assembly designated generally by reference numeral 10A. Cartridge assembly 10A includes two piston-type sub-assemblies 12A each having a container 14A and a plunger 16A. The containers 14A are formed as a unitary housing unit 18A having a connector 20A for stabilizing the containers 14A. The plungers 16A are connected to one another at a proximal end by stabilizing mount 21A. Each container 14A includes a nozzle 24A at a distal end and stores one of two protein solutions therein which form a biological adhesive when intermixed. As the unitary housing unit 18A is moved proximally towards the plungers 16A, proximal pressure is created within the containers 14A as the amount of area for storing the solutions is decreased to dispense the solutions in a drip-like manner from the nozzles 24A or from the drip applicator 34 as shown by FIG. 7A.

A fibrin sealant applicator spray gun designated generally by reference numeral 50 will now be discussed with reference to FIGS. 8-14B and in association with the cartridge assembly 10. As shown by FIGS. 8 and 8A, spray gun 50 includes a housing 52. Housing 52 includes an elongated body portion 54 defining a longitudinal axis and a stationary handle 56 projecting from elongated body portion 54. The stationary handle 56 includes a grip portion 58. The spray gun applicator 50

further includes a movable trigger handle 62 pivotally connected by pin 63 and camming bar 65 to the housing 52 adjacent the stationary handle 56 to form a pistol-type grip. The trigger handle 62 includes a gripping surface 64 and a channel 66 extending along the inner surface.

5 Body portion 54 contains a conically-shaped distal end 70 having a first and a second bore 72 and 74 (see FIG. 9) and a cavity 76. The first and second bores 72 and 74 cooperate in fluid communication with the nozzles 24 of the cartridge assembly 10 via passageways 71 and 73, respectively, when the cartridge assembly 10 is placed within the cavity 76 as shown by FIG. 11. Two stabilizer plates 78 extend
10 from a mid-section of the body portion 54 for firmly securing the unitary housing unit 18 of the cartridge assembly 10 when it is placed within the cavity 76. In addition, two tabs 37 protrude from the body portion 54 adjacent to an elongated, upside-down "V"-shaped protrusion 39 for aligning with the "V"-shaped notch 23 of the cartridge assembly 10 for securing the stabilizing mount 21 and maintaining the plungers 16
15 stationary during operation of the spray gun 50.

FIG. 8A illustrates the inner components of the fibrin sealant applicator spray gun 50 which includes a drive member assembly 60 and a release member assembly 68. The drive member assembly 60 includes camming bar 65, spring 67, plate 69, rod 75, channel 77 and rest member 79. An actuator 61 is secured to the
20 rod 75 by pins 81. The rod 75 traverses through the spring 67 and an opening in the plate 69. The plate 69 rests against rest member 79 when the trigger handle 62 is in the relaxed position. The plate 86 is curved slightly on the top portion toward the proximal end of the body portion 54. The top portion of the plate 86 bites on the rod 75, thereby preventing the rod 75 from being pulled distally as the trigger handle 62
25 is depressed and preventing the rod 75 from being pulled proximally when the trigger

handle 62 is moved to the relaxed position.

The release member assembly 68 includes release member 80, spring 84, release plate 86, support member 88 and curved plate stabilizer 90. The release member 80 traverses through an opening 92 in the housing 52, spring 84, and support member 88 such that the distal end of the release member 88 is adjacent release plate 86. The top part of the release plate 86 includes an opening from where the rod 75 passes through. The bottom part of the release plate 86 is supported by the curved plate stabilizer 90. In the rest position, the release plate 86 is situated at a slant with respect to the rod 75 to prevent the rod 75 from moving proximally.

In operation, the movable trigger handle 62 is depressed causing the camming bar 65 to push the plate 69 against the spring 67. As the plate 69 is pushed against the spring 67, the plate 69 grasps the rod 75 to pull the rod 75 distally within channel 77. Distal translation of the rod 75 causes distal translation of the actuator 61 of the drive member assembly 60. This causes the actuator 61 to distally push the connector head 20 to move the containers 14 distally to create positive pressure within the containers 14 while the plungers 16 are kept stationary by the tabs 37. The positive pressure within the containers 14 causes the protein solutions to be dispensed in a spray-like manner from bores 72 and 74 as shown by FIGS. 14 and 14A. It is contemplated that the drive member assembly 60 be designed in a manner to allow a specific amount of each solution to be dispensed from each container 14. For example, the drive member assembly 60 can be designed such that one-tenth cubic centimeter of each solution is dispensed from each container 14 when the movable trigger handle 62 is moved from the relaxed position to the fully depressed position.

When the movable trigger handle 62 is moved to the relaxed position, the camming bar 65 disengages the plate 69 and the plate 69 is pushed by the spring

67 against the rest member 79, as shown by FIG. 8A. When the movable trigger handle 62 is depressed again, the drive member assembly 60 further translates the actuator 61 distally to dispense the solutions within the containers 14 in the same manner as discussed above.

5 After the solutions have been dispensed from the containers 14, the release member assembly 68 is used to return the actuator 61 to the position shown in FIG. 8A in order to remove the cartridge assembly 10 and replace it with another cartridge assembly having protein solutions therein or to clean the fibrin spray gun 50. To return the actuator 61 to its original position, the release member 80 is
10 pushed distally to engage the release plate 86 and push it against the curved plate stabilizer 90, as shown by FIG. 14B. This causes the release plate 86 to become perpendicularly aligned with the rod 75 allowing the actuator 61 to be pulled proximally to its original position.

15 An alternate fibrin sealant spray gun is illustrated by FIG. 8B having a safety interlock mechanism 150 which includes a release arm 152 having a release arm pivot point 154 and a safety arm 156 having a safety arm pivot point 158. The release arm 152 includes a horizontal portion 160 and a vertical portion 162. When the safety arm 156 is positioned parallel to the rod 75, the safety arm 156 is wedged within safety notch 164 and the trigger handle 62 cannot be depressed.

20 In addition, when the safety arm 156 is positioned within safety notch 164, it makes contact with the vertical portion 162 of the release arm 152 to pivot the release arm 152. The horizontal portion 160 of the release arm 152 then makes contact with the plate 86 and pushes the plate 86 against the curved plate stabilizer 90. The actuator 61 is then released and can be pulled proximally to the position
25 shown in FIG. 8B. The safety arm 156 is then pivoted away from the safety notch

164 to disengage the release arm 152 from the plate 86 and permit plate 86 to bite into rod 75 to prevent the rod 75 from being moved proximally.

A second embodiment of the cartridge assembly is shown by FIGS. 15-23 and designated generally by reference numeral 100. Cartridge assembly 100 includes a drip conversion accessory 102 pivotable between a drip position for dispensing the solutions in a drip-like manner and a non-drip position. As shown by FIG. 16A, drip conversion accessory 102 is attached to containers 104 by pin 106 traversing extensions 107 and ferrule 109. Drip conversion accessory 102 includes two nozzle receiving portions 108 for receiving two nozzles 110 extending downwardly from containers 104 when the conversion accessory 102 is in the drip position. Each nozzle receiving portion 108 is in fluid communication with one passageway 112 (see FIGS. 17 and 18). The passageways 112 are in fluid communication with a dispensing member 113 having two passageways 115 for dispensing the solutions onto the application site as an actuator 114 is moved proximally towards stationary plungers 116 as shown by FIGS. 19-22.

When the drip conversion accessory 102 is in the non-drip position as shown by FIG. 23, the cartridge assembly 100 is adaptable for placement into a fibrin spray gun applicator designated generally by reference numeral 120 in FIG. 24 for dispensing the solutions in a spray-like manner as shown by FIG. 25.

With reference to FIGS. 26 and 27-27A, there is shown cartridge assembly 10 mounted onto the coupler unit 26 which includes a compartment 22 for receiving vials 25 storing solutions therein. The aspirating needles 27 are situated at the base 94 of the compartment 22 for piercing a protective sealant 31 on each vial 25 and for dispensing the solutions within containers 14 via nozzles 206. The coupler unit 26 includes a lid 28 having a protrusion 30 for pushing the vials 25 onto the tips

of the aspirating needles 27 when the lid 28 is closed and locking the vials 25 within the compartment 22. Coupler unit 26 further includes a safety mount protrusion 29 which is shaped as an upside-down "V" on lip 208 to align with the "V"-shaped notch 23 on the stabilizer mount 21 of the cartridge assembly 10 only if the cartridge assembly 10 matingly engages the nozzles 206 of the coupler unit 26 in a proper orientation, as shown by FIG. 26A. Therefore, the safety mount protrusion 29 prevents the protein solutions in the vials 25 to be accidentally dispensed to the wrong containers 14.

To dispense the solutions to the containers 14, the connector head 20 is moved proximally to increase the area within the containers 14. This creates downward pressure which forces the solutions to flow through passageways 206 and be dispensed through nozzles 24 into the cartridge assembly 10 as shown by FIG. 27A. The coupler unit 26 is then removed from the cartridge assembly 10 and disposed of to prevent contamination. It is also contemplated that the coupler unit 26 can be resterilized for multiple uses.

When the solutions have been depleted from within the containers 14, a new coupler unit 26 having a new set of vials can be reloaded to the cartridge assembly 10 to replenish the solutions. After use, the assembly 10 can be disposed of or the assembly 10 can be cleaned and reused with different component solutions.

It is contemplated that coupler unit 26 can also be used to dispense medication or other fluids into a syringe for medicinal or irrigation purposes. It is also contemplated to provide coupler unit 26 with more than two compartments. It is further contemplated to place vials having freeze-dried powders into the compartments 22 and dispense sterile water or other fluid from a syringe or assembly 10 into the vials via nozzles 206 to mix with the freeze-dried powders. The solutions can then be

dispensed into assembly 10 as discussed above. Further still, it is contemplated for the coupler unit 26 to have a transparent housing for viewing the amount and type of contents within the vials 25.

A first alternative embodiment for the coupler unit is shown by FIG. 26B and designated generally by reference numeral 530. Coupler unit 530 includes a body portion 532 and a drawer assembly 534 shown in FIG. 26C. Body portion 532 includes an upper channel 535, a lower channel 536, two compartments 537 having two aspirating needles (not shown), two nozzles 538, and a latching assembly 539. Drawer assembly 534 includes two vial-receiving compartments 540, an upper elongated member 541 for matingly cooperating with upper channel 535 and a lower elongated member 542 for matingly cooperating with lower channel 536, and a lid 543 for closing compartments 537 when the drawer assembly 534 is in the closed position and for pushing the vials into the aspirating needles.

When the drawer assembly 534 is in the closed position, the upper elongated member 541 lifts staple 544 and locks staple 544 against extension 545 such that staple 544 tightly holds the nozzles 24 of cartridge assembly 10 inserted within latching assembly 539. The solutions are dispensed within the containers 14 as discussed above with respect to the embodiment shown by FIGS. 26-26A and 27-27A.

A second alternative embodiment for the coupler unit is shown by FIGS. 26D and 26E and designated generally by reference numeral 650. Coupler unit 650 includes a housing 652 having a flip-top housing lid 654 and a stationary lid 655, a needle assembly 656, and a manifold assembly 658. Housing 652 includes a hinge 660 for opening the housing 652 and placing the vials 25 within vial-receiving compartments 662 and 664. Once the vials 25 are placed within the compartments 662 and 664, the flip-top housing lid 654 is closed. The manifold assembly 658 is

then pushed toward the vials 25 such that two aspirating needles 666 of the needle assembly 656 pierce the protective seal of the vials 25 to establish fluid communication between the vials 25 and the manifold assembly 658. The manifold assembly 658 includes a locking bar 668 which goes over the flip-top housing lid 654 when the manifold assembly 658 is pushed toward the vials 25 to lock the lid 654 and prevent it from opening during dispensing. The coupler unit 650 can accommodate vials having various volumetric capacities, since the manifold assembly 658 is movable relative to the housing 652. The solutions are dispensed within the containers 14 as discussed above with respect to the embodiment shown by FIGS. 26-26A and 27-27A.

With reference to FIG. 28 a fourth embodiment of a cartridge assembly designated generally by reference numeral 250 is shown. Cartridge assembly 250 includes two piston-type sub-assemblies 252 each having a container 254 and a plunger 256. The containers 254 are formed as a unitary housing unit 258 having a connector 260 for stabilizing the containers 254. The plungers 256 are connected to one another at a proximal end by connector 262. Each plunger 256 includes a nozzle 264 at a distal end in fluid communication with a respective pathway (not shown) within each plunger 256. Each container 254 stores one of two protein solutions therein which form a biological adhesive when intermixed. As the plungers 256 are moved proximally with the aid of connector 262, proximal pressure is created within the containers 254 as the amount of area for storing the solutions is decreased to dispense the solutions into the pathways. The solutions are then transported via the pathways to the nozzles 264 and are dispensed onto an application site in a drip-like manner, as shown by FIG. 28. It is also contemplated to operate cartridge assembly 250 by distally moving the unitary housing unit 258 while keeping the plungers 256

stationary.

Referring now to FIG. 29 there is shown a fifth embodiment of a cartridge assembly designated generally by reference numeral 300. The cartridge assembly 300 includes an actuator 302 having a drip conversion accessory 304 attached to a plunger assembly 305. The cartridge assembly further includes a unitary container unit 306 having two containers 308. The containers 308 are connected at a proximal end by a connector 310. As actuator 302 is moved proximally, the area within the containers 308 storing the solutions is decreased creating pressure which forces the solutions to flow distally through passageways within the plunger assembly 305 and the actuator 302 and be dispensed from dispensing member 310. It is also contemplated to operate cartridge assembly 300 by distally moving the unitary container unit 306 while keeping the drip conversion accessory 304 stationary.

The drip conversion accessory 304 is identical to the drip conversion accessory 102 described above. The solutions are dispensed from the drip conversion accessory 304 as described above and are dripped onto the application site. It is contemplated to provide a fibrin spray gun applicator dimensioned to receive cartridge assembly 300 to dispense the solutions in a spray-like manner.

FIGS. 30-34 illustrate two alternate embodiments for the conically-shaped distal end 70 of the fibrin spray gun applicator shown in FIG. 8. FIGS. 30-32 illustrate a first alternative embodiment where the spray gun 50 includes a conically-shaped distal end 400 having two spray atomizers 402 in fluid communication with the nozzles 24 of the cartridge assembly 10 via two pathways 404, two atomizer assemblies 406, and two chambers 408. Each atomizer assembly 406 includes a ball 410 and a spring 412 having a specific spring constant, as shown by the cross-sectional view of FIG. 31, for dispensing the solutions as an atomized mist.

In operation, the movable trigger handle 62 is depressed causing the protein solutions to be dispensed into the chambers 408 creating pressure against the balls 410. When the pressure created exceeds the amount of pressure the springs 412 can withhold, the balls 410 are pushed distally and the solutions flow into pathways 404 and are dispensed by the spray atomizers 402 as an atomized mist. The spray atomizers 402 are angled toward each other to permit intermixing of the solutions in the air and on the application site.

With reference to FIGS. 32-34, a second alternate embodiment is shown for the conically-shaped distal end 70 of the spray gun 50. Similarly, to the first alternative embodiment discussed above, this embodiment includes a conically-shaped distal end 500 having two spray atomizers 502 in fluid communication with the nozzles 24 of the cartridge assembly 10 via two pathways 504, two atomizer assemblies 506, and two chambers 508. Each atomizer assembly 506 includes a ball 510 and a spring 512 having a specific spring constant, as shown by the cross-sectional view of FIG. 33, for dispensing the solutions as an atomized mist.

The second alternate embodiment for the distal end further includes a hinge assembly 514 allowing a portion of the distal end 500 to pivot downwards for dispensing the protein solutions in a stream. Hence, the second alternate embodiment allows for two modes of operation for the solutions to be dispensed as an atomized mist and in a stream.

In the first mode of operation, similarly to the method of operation for the first alternate embodiment, the movable trigger handle 62 is depressed causing the protein solutions to be dispensed into the chambers 508 creating pressure against the balls 510. When the pressure created exceeds the amount of pressure the springs 512 can withhold, the balls 510 are pushed distally and the solutions flow into pathways

504 and are dispensed by the spray atomizers 502 as an atomized mist. The spray atomizers 502 are angled toward each other to permit intermixing of the solutions in the air and on the application site.

5 In the second mode of operation, the hinge assembly 514 is pivoted downwards to disengage the spray atomizers 502, the pathways 504 and the chambers 508 from being in fluid communication with the nozzles 24. When the movable trigger handle 62 is depressed, the solutions are dispensed in a stream.

10 FIG. 34A is a side view showing a second portion 515 of the distal end of the fibrin gun applicator being pivotable via pivot point 516 for ease of cartridge insertion and removal. FIGS. 34B and 34C are side and a perspective views, respectively, of an alternate embodiment of the fibrin sealant applicator having a pivotable distal end 518 via pivot point 520 for ease of cartridge insertion and removal.

15 The present invention also provides a kit for applying a solution of fibrinogen and a solution of thrombin on a wound to stop bleeding or the like. The kit includes a cartridge assembly and a spray gun applicator configured to receive the cartridge assembly and to dispense the solutions stored within the cartridge assembly.

20 With reference to FIGS. 35-37A there are shown various embodiments of dripper tip cannula assemblies for matingly engaging the nozzles 24 of the cartridge assembly 10 for applying a fibrin sealant during laparoscopic procedures. FIG. 35 is a front view of a first embodiment of the distal end of a dripper tip cannula assembly designated by reference numeral 550 for connection to the cartridge assembly of FIG. 1. Dripper tip cannula assembly 550 includes two orifices 552 and 554 at the distal end of cannula channels 556 and 558, respectively, as shown by FIG. 25 35A. The distal end of cannula assembly 550 is configured to dispense the solutions

towards one another to permit mixing of the solutions on the application site.

FIG. 36 is a front view of a second embodiment of the distal end of a dripper tip cannula assembly designated by reference numeral 570 for connection to the cartridge assembly of FIG. 1. Dripper tip cannula assembly 570 includes two orifices 572 and 574 at the distal end of cannula channels 576 and 578, respectively, as shown by FIG. 36A. The distal end of cannula assembly 570 is configured to dispense the solutions towards one another to permit mixing of the solutions on the application site.

FIG. 37 is a front view of a third embodiment of the distal end of a dripper tip cannula assembly designated by reference numeral 600 for connection to the cartridge assembly of FIG. 1. Dripper tip cannula assembly 600 includes two orifices 602 and 604 at the distal end of cannula channels 606 and 608, respectively, as shown by FIG. 37A. The distal end of cannula assembly 600 is configured to dispense the solutions towards one another to permit mixing of the solutions on the application site.

With reference to FIG. 38 there is shown a perspective view of a dripper assembly designated generally by reference numeral 700 having a cartridge assembly mounting configuration 702 for insertion of the cartridge assembly of FIG. 1 therein as shown by FIG. 39. Dripper assembly 700 further includes a stationary finger rest 704 and a dripper 706 at a distal end having two nozzles 708 in fluid communication with two passageways 710 which lead to two openings 712 for matingly cooperating with the nozzles 24 of the cartridge assembly 10. Dripper assembly 700 also includes two cut-out regions 714 for viewing the contents within the containers 14.

In operation, the user rests his two index fingers on the finger rest 704

and using his thumbs pushes the containers 14 towards the plungers 16 to dispense the solutions in a drip-like manner from the dripper 706.

With reference to FIG. 40 there is shown a cross-sectional view of a sprayer assembly designated generally by reference numeral 750 having a cartridge assembly mounting configuration 752 for insertion of the cartridge assembly of FIG. 1 therein. Sprayer assembly 750 further includes a stationary finger rest 754 and a sprayer 756 at a distal end having two nozzles 758 in fluid communication with two passageways 760 which lead to two openings 762 for matingly cooperating with the nozzles 24 of the cartridge assembly 10. An enlarged cross-sectional view of the sprayer 756 is shown by FIG. 41. Sprayer assembly 750 also includes two cut-out regions 764 for viewing the contents within the containers 14.

In operation, similarly to the dripper assembly operation, the user rests his two index fingers on the finger rest 754 and using his thumbs pushes the containers 14 towards the plungers 16 to dispense the solutions in a spray-like manner from the sprayer 756. It is contemplated to provide sprayer assembly 750 with a removable sprayer at the distal end for connecting a dripper or any other type of dispensing assembly to the distal end.

Referring now to FIG. 42, there is shown a perspective view of a dripper assembly designated generally by reference numeral 800 having an unclogging system 802 in engagement with housing 803. The unclogging system 802 is moveable between a clogging position and an unclogging position as shown by the cross-sectional views of FIGS. 43 and 44, respectively, via a spring mechanism 804 having two clamps 806 in engagement with a first set of indents 808 (unclogging position) or a second set of indents 810 (clogging position) on the housing 803. The dripper assembly 800 further includes two nozzle-receiving apertures 812 for placement of the

nozzles 24 of cartridge assembly 10 therein. Two passageways 814 and 816 lead from each nozzle-receiving aperture 812 to a lumen system 818 in fluid communication with the distal end 820 of the dripper assembly 800. The lumen system 818 includes a central lumen rod 822 having a lumen 824 therein and an outer lumen rod 826 having an outer lumen 828. The lumens 824 and 828 are concentrically oriented as shown by the cross-sectional view of FIG. 45.

In operation, the unclogging system 802 can be in the clogging position or the unclogging position, depending on whether mixing of the thrombin and fibrinogen is desired to occur within the distal end 820 of the dripper assembly 800 or external to the dripper assembly 800. If the dripper assembly 800 is operated in the clogging position, then clogging would occur within the distal end 820 of the assembly 800. To remove any clogging that has occurred, the unclogging system 802 is moved to the unclogging position, in order for the central lumen rod 822 to push the clogged material away from the distal end 820 to unclog the dripper assembly 800 as shown by FIG. 44.

It is contemplated to coat the distal end 820 of the dripper assembly 800 with a non-stick polymer to prevent the clogging material from attaching to the distal end 820 for allowing the distal end 820 to be easily cleaned.

It is further contemplated to provide cartridge assemblies which are different from the cartridge assemblies disclosed herein but operate in substantially the same manner. Therefore, it is understood that various modifications may be made to the embodiments disclosed herein. For example, while specific preferred embodiments of the cartridge assembly, coupler unit, drip conversion accessory, spray gun applicator, and dripper tip cannula assemblies have been described in detail, structures that perform substantially the same function in substantially the same way

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to achieve substantially the same result can also be used. Also, besides applying a fibrin sealant, the fibrin sealant spray gun applicator and cartridge assembly can be used to perform human or veterinary surgical procedures, such as applying antiseptics and medication. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the above disclosure and claims appended hereto.

WHAT IS CLAIMED IS:

1. A fibrin sealant applicator kit for applying a solution of fibrinogen and a solution of thrombin, which comprises:

5 a cartridge assembly having two containers, one for storing the solution of fibrinogen and one for storing the solution of thrombin, two pistons in alignment with the containers, and a conduit assembly having two conduits, one conduit in fluid communication with the container storing the solution of fibrinogen and one conduit in fluid communication with the container storing the solution of thrombin; and

10 a spray gun applicator having a housing which includes an elongated body portion defining a longitudinal axis and a stationary handle projecting from elongated body portion, the spray gun applicator further including a movable trigger handle pivotally connected to the housing adjacent the stationary handle to form a pistol-type grip, body portion contains a cavity configured to receive the
15 cartridge assembly and having a drive member assembly operatively associated with an actuator for controlling the movement of the actuator along the cavity as the trigger handle is depressed, the actuator pushing the containers towards the pistons to decrease the volumetric capacity of the containers to separately dispense each of the solutions through a respective one of said two conduits.

20 2. The fibrin sealant applicator kit according to Claim 1, wherein each of the conduits is in fluid communication with one of two nozzles at a distal end of the spray gun via a respective channel for dispensing each of the solutions on an application site from the nozzles in a spray-like manner.

3. The fibrin sealant applicator kit according to Claim 1, wherein the spray gun further two stabilizer plates protruding from a mid-section of the body portion for engaging the containers to stabilize the cartridge assembly when the cartridge assembly is placed within the cavity.

5 4. The fibrin sealant applicator kit according to Claim 1, wherein approximately one-tenth cubic centimeter of each solution is dispensed from each container when the trigger is moved from a stationary position to a fully depressed position.

10 5. The fibrin sealant applicator kit according to Claim 1, wherein the spray gun further includes a locking mechanism operatively associated with the actuator for preventing the actuator from moving proximally along the cavity.

15 6. The fibrin sealant applicator kit according to Claim 5, wherein the spray gun further includes a release member assembly operatively associated with the locking mechanism for disengaging the locking mechanism to allow the actuator to move proximally along the cavity.

20 7. The fibrin sealant applicator kit according to Claim 2, wherein the spray gun further includes a drip conversion accessory having two nozzle receiving portions for aligning with the nozzles when the drip conversion accessory is in a drip position, each of the nozzle receiving portions are in fluid communication with one passageway, each of the passageways are in fluid communication with one conduit for dispensing the solutions onto an application site in a drip-like manner as the actuator

is moved along the channel and the drip conversion accessory is in the drip position.

8. The fibrin sealant applicator kit according to Claim 2, wherein the spray gun further includes an atomizer having two atomizing assemblies in fluid communication with the nozzles for dispensing the solutions as atomized mists.

5 9. The fibrin sealant applicator kit according to Claim 8, wherein the atomizer is pivotable from an atomizing position to a non-atomizing position, in the non-atomizing position the atomizing assemblies are not in fluid communication with the nozzles.

10 10. The fibrin sealant applicator kit according to Claim 8, wherein each of the atomizing assemblies include a ball at a proximal end of a spring, each ball blocking the flow of one of the solutions as the solutions are dispensed from the nozzles creating pressure between the nozzles and the balls until the pressure created exceeds a predetermined amount of pressure the spring can withhold, wherein the solutions distally push the balls allowing the solutions to be dispensed from the
15 atomizer as atomized mists.

11. The fibrin sealant applicator kit according to Claim 1, wherein each conduit is in fluid communication with a respective cartridge nozzle at a distal end of the cartridge assembly.

12. The fibrin sealant applicator kit according to Claim 11, further including a drip applicator having two proximal openings and two distal openings, the proximal openings being in fluid communication with the distal openings through two pathways therein, the proximal openings further being configured to matingly engage the cartridge nozzles for being in fluid communication with the conduits for dispensing the solutions in a drip-like manner as the volumetric capacity of the containers is decreased by means other than the actuator of the spray gun.

13. The fibrin sealant applicator kit according to Claim 12, wherein the distal openings are adjacent to one another for allowing the solutions to intermix as the solutions exit the distal openings.

14. The fibrin sealant applicator kit according to Claim 1, wherein the spray gun includes a safety mount protrusion for matingly engaging a safety mount indent on the cartridge assembly if the cartridge assembly is positioned and received by the spray gun in a particular orientation, the safety mount protrusion preventing the cartridge assembly from being received by the spray gun if the cartridge assembly is positioned in an orientation other than the particular orientation.

15. The fibrin sealant applicator kit according to Claim 1, further including a dripper tip cannula assembly having two cannula channels, each cannula channel including a proximal opening and a distal opening, the proximal openings being configured to matingly engage the cartridge nozzles for being in fluid communication with the conduits for dispensing the solutions from the distal openings as the volumetric capacity of the containers is decreased.

16. The fibrin sealant applicator kit according to Claim 15, wherein the cannula channels are oriented to dispense the solutions from the distal openings towards one another to permit mixing of the solutions on the application site.

5 17. The fibrin sealant applicator kit according to Claim 1, further including a coupler unit having a compartment for receiving vials storing the solutions therein and a mounting assembly for mounting the cartridge assembly to the coupler unit where the conduit assembly of the cartridge assembly is in fluid communication with a conduit assembly of the coupler unit, the coupler unit further having two
10 aspirating needles each having a channel therein in fluid communication with the conduit assembly of the coupler unit, each aspirating needle pierces a sealant on each vial to dispense the solutions from the coupler unit to the containers of the cartridge assembly via the conduit assembly of the coupler and the conduit assembly of the cartridge assembly as downward pressure is applied to the solutions within the vials.

15 18. The fibrin sealant applicator kit according to Claim 17, wherein the coupler unit includes a lid for closing the compartment, the lid having locking structure for pushing the vials onto the aspirating needles when the lid is closed for the aspirating needles to pierce the sealants on the vials and for locking the vials within the compartment.

19. A fibrin sealant cartridge assembly for applying a solution of fibrinogen and a solution of thrombin, which comprises:

5 a container unit having a first and a second container, the first container storing the solution of fibrinogen and the second container storing the solution of thrombin;

a first and a second piston matingly cooperating with the first and the second container, respectively; and

10 a conduit assembly having a first and a second conduit, the first conduit extending within the first piston and in fluid communication with the first container, the second conduit extending within the second piston and in fluid communication with the second container, wherein translation of the container unit towards the first and the second pistons decreases the volumetric capacity of the first and the second container forcing the solutions therein to flow within the first and the second conduit and be dispensed from a distal end of the cartridge assembly.

15 20. The fibrin sealant cartridge assembly according to Claim 19, wherein the first and the second conduit are in fluid communication with a first and a second cartridge nozzle, respectively, at the distal end of the cartridge assembly for dispensing the solutions from the first and the second cartridge nozzles.

20 21. The fibrin sealant cartridge assembly according to Claim 20, further including a drip applicator having a first and a second proximal opening and a first and a second distal opening, the first and the second proximal opening being in fluid communication with the first and the second distal opening, respectively, through a first and a second pathway therein, the first and second proximal opening

further being configured to matingly engage the first and the second cartridge nozzle, respectively, for being in fluid communication with the first and the second conduit for dispensing the solutions in a drip-like manner as the volumetric capacity of the first and the second container is decreased.

5 22. The fibrin sealant cartridge assembly according to Claim 21, wherein the first and the second distal opening are adjacent to one another for allowing the solutions to intermix as the solutions exit the first and the second distal opening.

10 23. The fibrin sealant cartridge assembly according to Claim 19, further including a dripper tip cannula assembly having two cannula channels, each cannula channel including a proximal opening and a distal opening, the proximal openings being configured to matingly engage the cartridge nozzles for being in fluid communication with the conduits for dispensing the solutions from the distal openings as the volumetric capacity of the containers is decreased.

15 24. The fibrin sealant cartridge assembly according to Claim 19, further including a coupler unit having a compartment for receiving vials storing the solutions therein and a mounting assembly for mounting the cartridge assembly to the coupler unit where the conduit assembly of the cartridge assembly is in fluid communication with a conduit assembly of the coupler unit, the coupler unit further
20 having two aspirating needles each having a channel therein in fluid communication with the conduit assembly of the coupler unit, each aspirating needle pierces a sealant on each vial to dispense the solutions from the coupler unit to the containers of the

cartridge assembly via the conduit assembly of the coupler and the conduit assembly of the cartridge assembly as pressure is applied to the solutions within the vials.

25. A fibrin sealant spray gun applicator for applying a solution of fibrinogen and a solution of thrombin and configured for receiving a cartridge assembly having two containers, one for storing the solution of fibrinogen and one for storing the solution of thrombin, two pistons in alignment with the containers, and a conduit assembly having two conduits, one conduit in fluid communication with the container storing the solution of fibrinogen and one conduit in fluid communication with the container storing the solution of thrombin, the fibrin sealant spray gun applicator comprising:

a housing which includes an elongated body portion defining a longitudinal axis and a stationary handle projecting from elongated body portion, the body portion including a cavity configured to receive the cartridge assembly;

a movable trigger handle pivotally connected to the housing adjacent the stationary handle to form a pistol-type grip; and

a drive member assembly operatively associated with an actuator for controlling the movement of the actuator along the cavity as the trigger handle is depressed, the actuator pushing the containers towards the pistons to decrease the volumetric capacity of the containers to dispense each of the solutions through a respective one of said two conduits.

26. The fibrin sealant applicator spray gun according to Claim 25, wherein each of the conduits is in fluid communication with one of two nozzles at a distal end of the spray gun via a respective channel for dispensing each of the

solutions on an application site from the nozzles in a spray-like manner.

27. The fibrin sealant applicator spray gun according to Claim 25,
wherein the spray gun further two stabilizer plates protruding from a mid-section of
the body portion for engaging the containers to stabilize the cartridge assembly when
the cartridge assembly is placed within the cavity.

28. The fibrin sealant applicator spray gun according to Claim 25,
wherein approximately one cubic centimeter of each solution is dispensed from each
container when the trigger is moved from a stationary position to a fully depressed
position.

29. The fibrin sealant applicator spray gun according to Claim 25,
wherein the spray gun further includes a locking mechanism operatively associated
with the actuator for preventing the actuator from moving proximally along the
cavity.

30. The fibrin sealant applicator spray gun according to Claim 29,
wherein the spray gun further includes a release member assembly operatively
associated with the locking mechanism for disengaging the locking mechanism to
allow the actuator to move proximally along the cavity.

31. The fibrin sealant applicator spray gun according to Claim 26, wherein the spray gun further includes a drip conversion accessory having two nozzle receiving portions for aligning with the nozzles when the drip conversion accessory is in a drip position, each of the nozzle receiving portions are in fluid communication with one passageway, each of the passageways are in fluid communication with one conduit for dispensing the solutions onto an application site in a drip-like manner as the actuator is moved along the channel and the drip conversion accessory is in the drip position.

32. A fibrin sealant applicator kit for applying a solution of fibrinogen and a solution of thrombin, which comprises:

a cartridge assembly having two containers, one for storing the solution of fibrinogen and one for storing the solution of thrombin, two pistons in alignment with the containers, and a conduit assembly having two conduits, one conduit in fluid communication with the container storing the solution of fibrinogen and one conduit in fluid communication with the container storing the solution of thrombin; and

a dispensing assembly having a housing which includes an elongated body portion defining a longitudinal axis, the housing contains a cavity configured to receive the cartridge assembly and two openings at a distal end in fluid communication with the two conduits, wherein upon pushing the containers towards the pistons the volumetric capacity of the containers decreases to simultaneously dispense each of the solutions through a respective one of said two openings.

33. The fibrin sealant applicator kit according to Claim 32, wherein each of the openings is in fluid communication with one of two nozzles at a distal end of the dispensing assembly via a respective channel for dispensing each of the solutions on an application site from the nozzles.

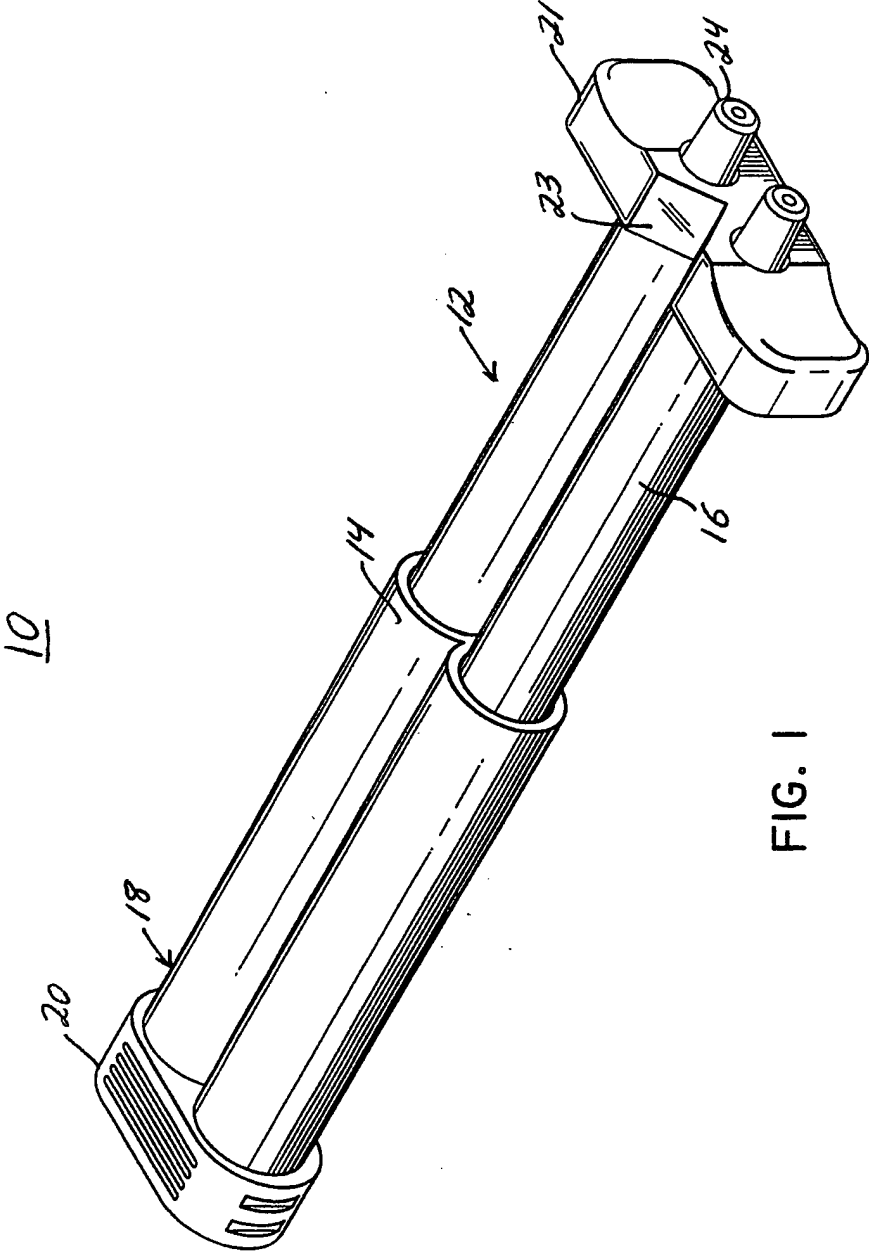
5 34. The fibrin sealant applicator kit according to Claim 33, wherein the solutions are dispensed on the application site from the nozzles in a spray-like manner.

10 35. The fibrin sealant applicator kit according to Claim 33, wherein the solutions are dispensed on the application site from the nozzles in a drip-like manner.

36. The fibrin sealant applicator kit according to Claim 32, wherein the dispensing assembly is unitary.

15 37. The fibrin sealant applicator kit according to Claim 32, wherein the dispensing assembly further includes an unclogging system having unclogging structure moveable from a clogging position to an unclogging position for causing the solutions to mix within the dispensing assembly or outside the dispensing assembly, respectively.

38. A dispensing assembly having a housing which includes an elongated body portion defining a longitudinal axis, the housing contains a cavity configured to receive a cartridge assembly of the type having two containers, one for storing a solution of fibrinogen and one for storing a solution of thrombin, two
5 pistons in alignment with the containers, and a conduit assembly having two conduits, one conduit in fluid communication with the container storing the solution of fibrinogen and one conduit in fluid communication with the container storing the solution of thrombin, the dispensing assembly further having two openings at a distal
10 end in fluid communication with the two conduits, wherein upon pushing the containers towards the pistons the volumetric capacity of the containers decreases to simultaneously dispense each of the solutions through a respective one of said two openings.



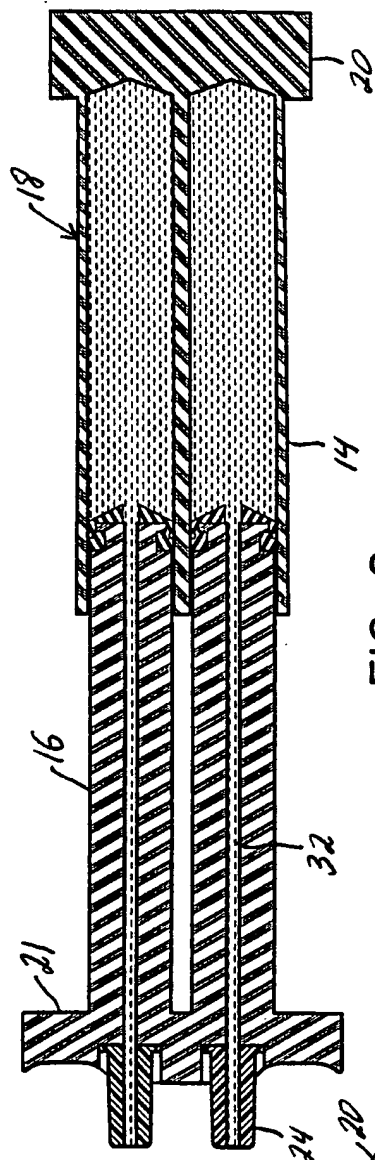


FIG. 2

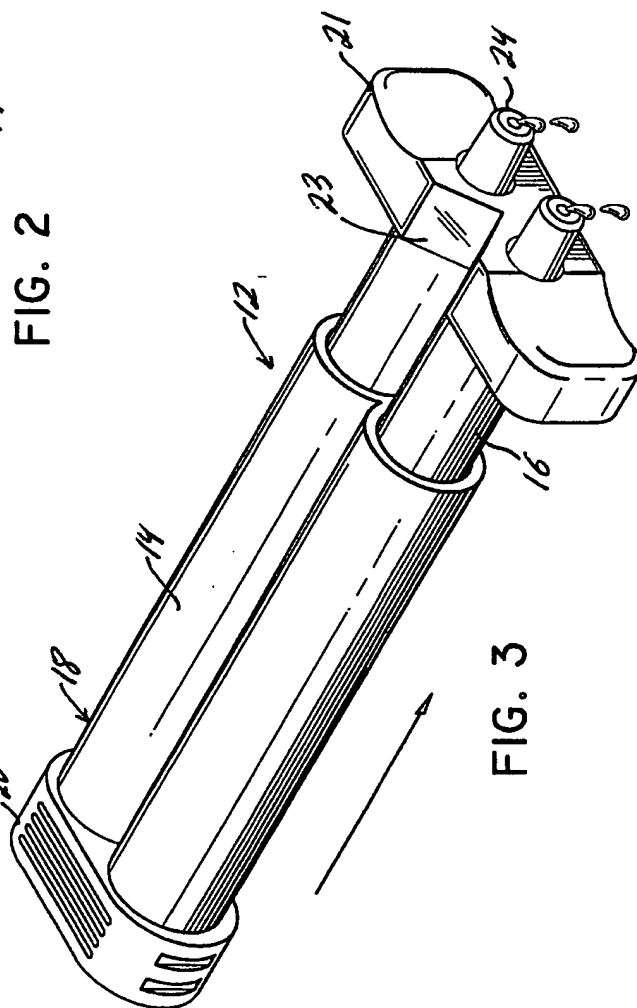


FIG. 3

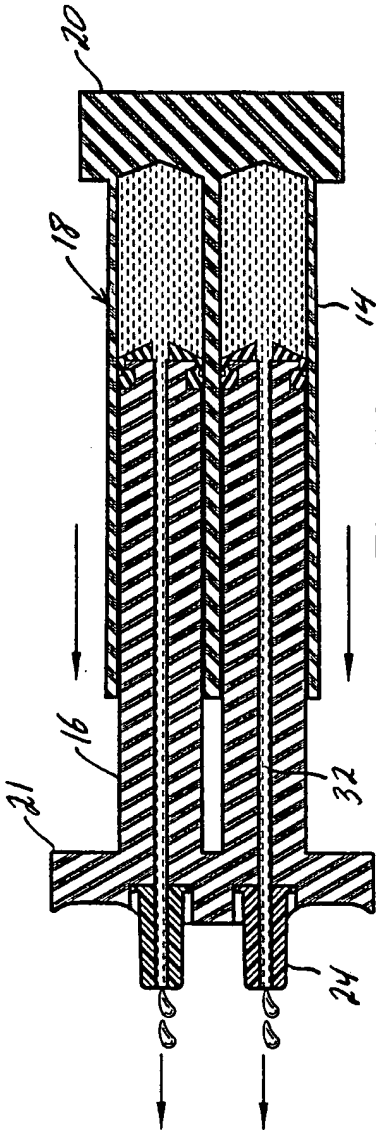


FIG. 3A

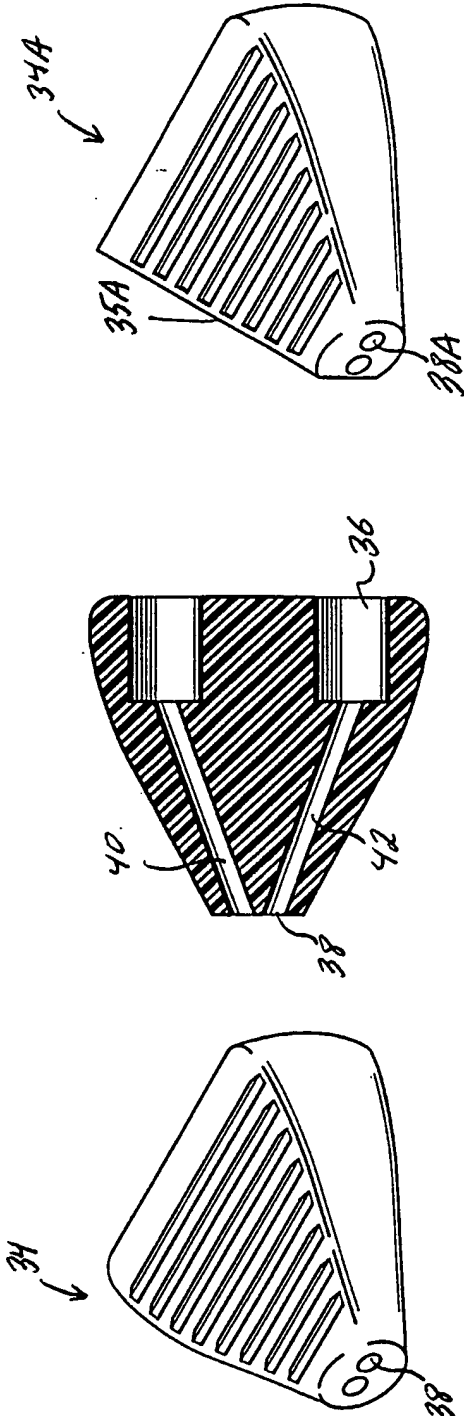
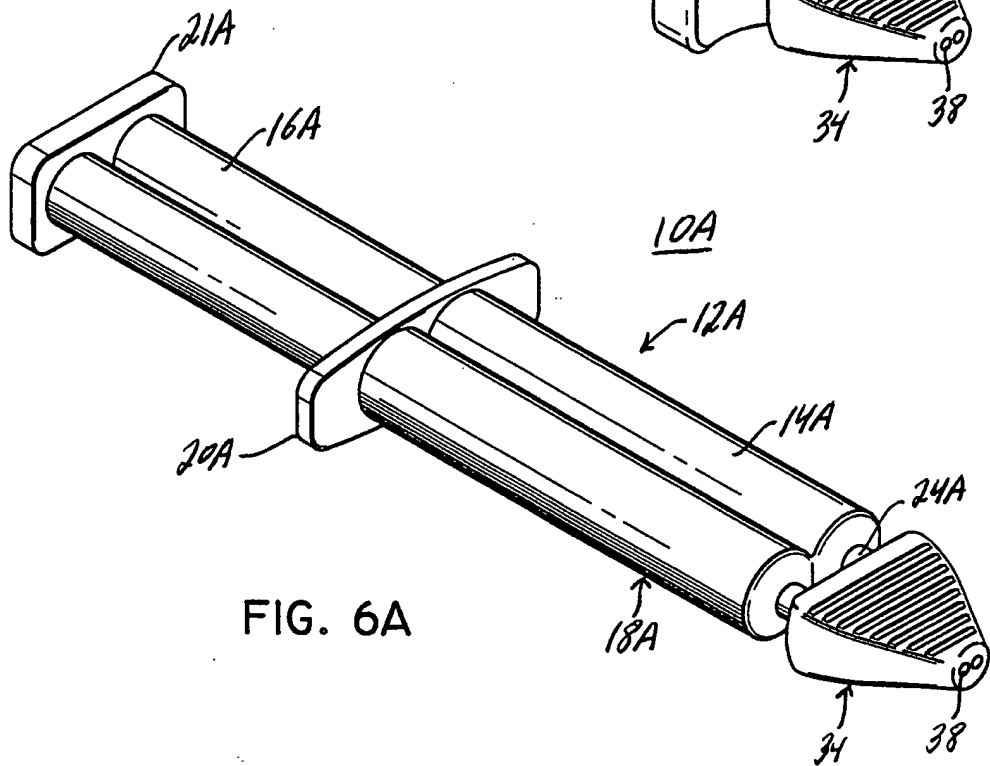
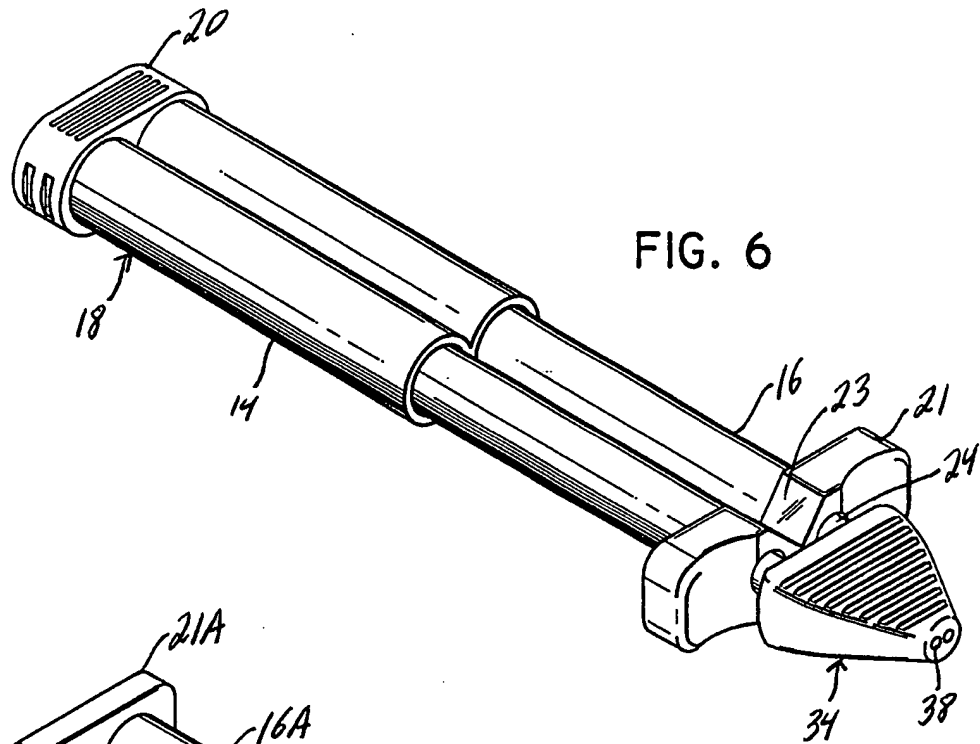
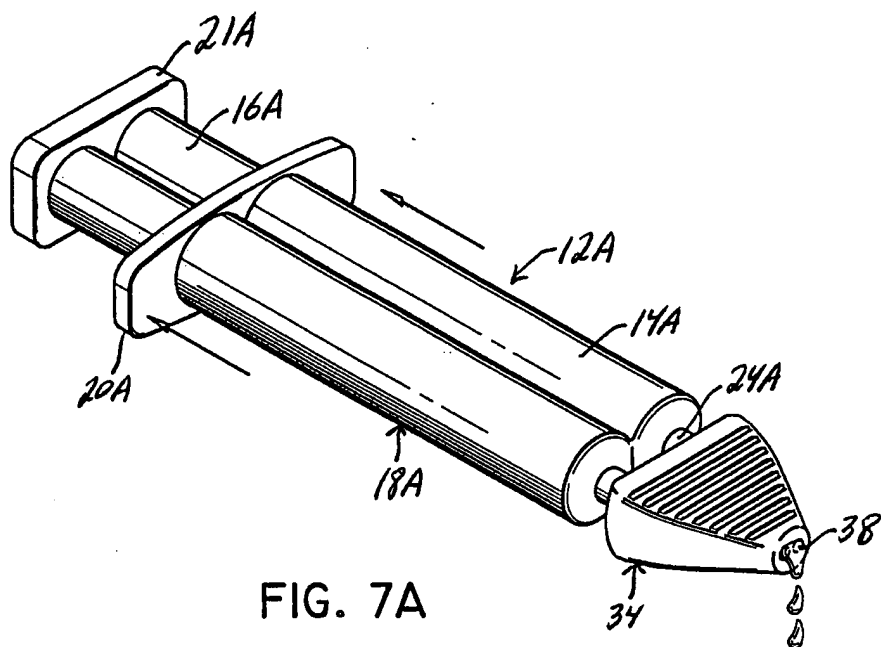
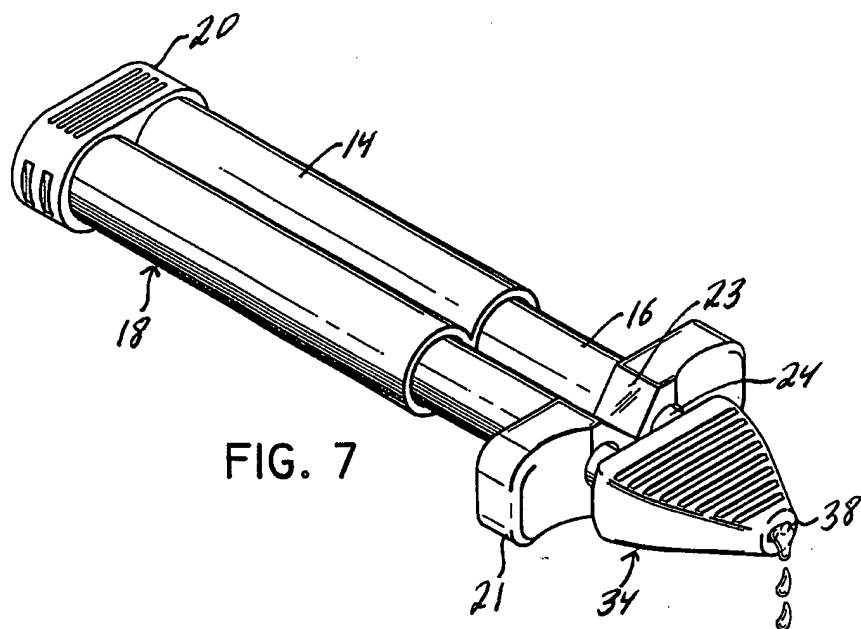


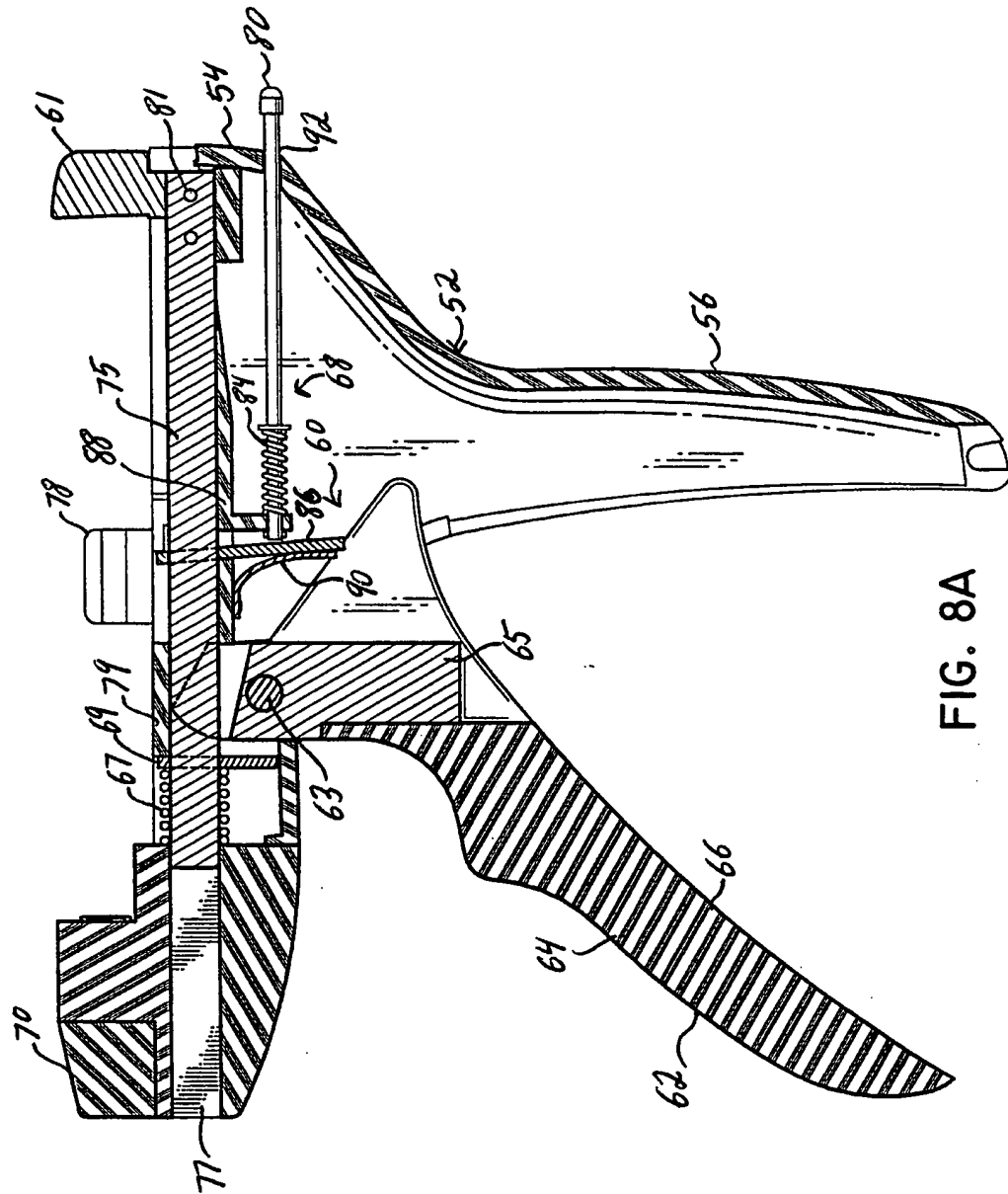
FIG. 4

FIG. 5

FIG. 5A







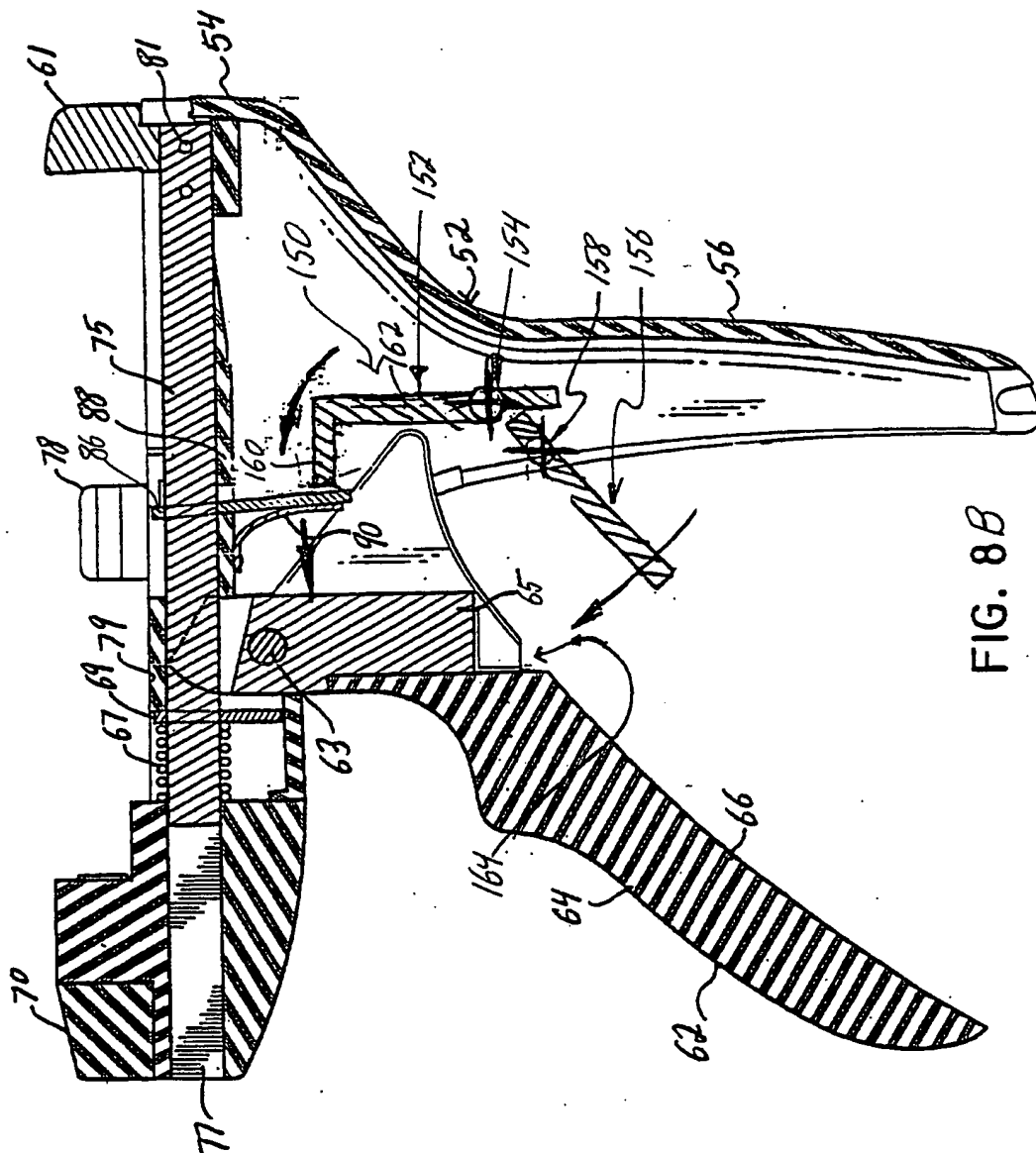
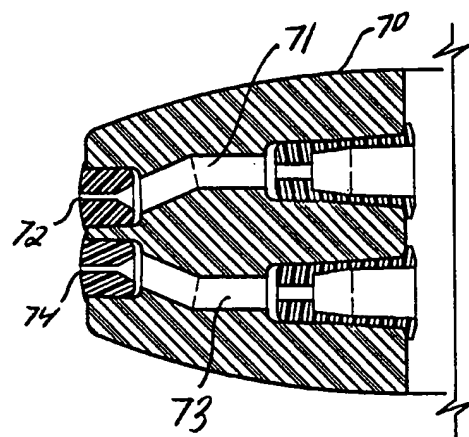
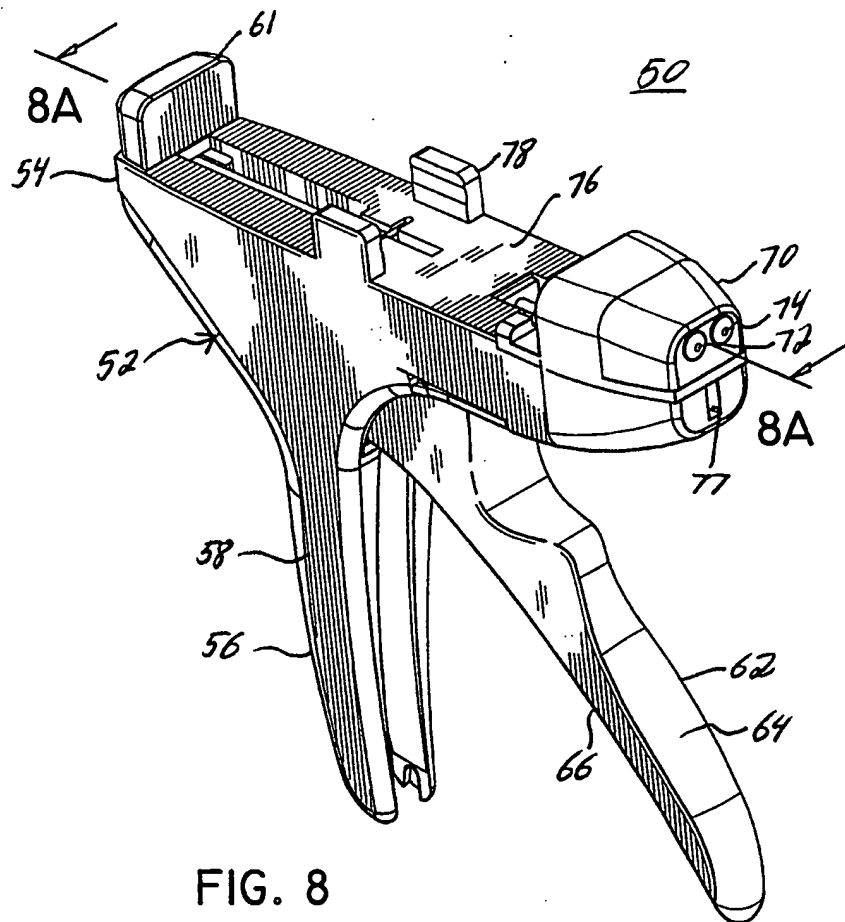


FIG. 88



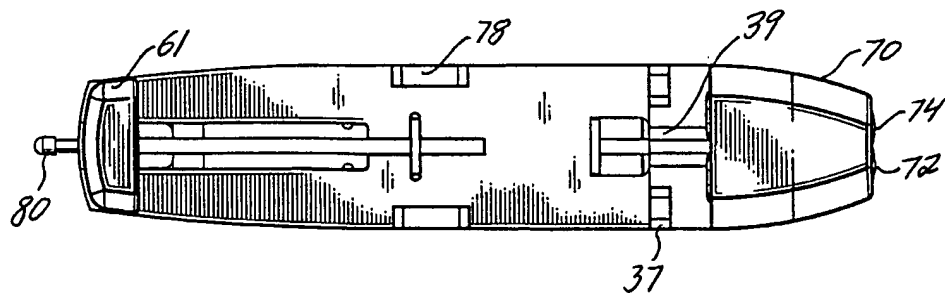


FIG. 10

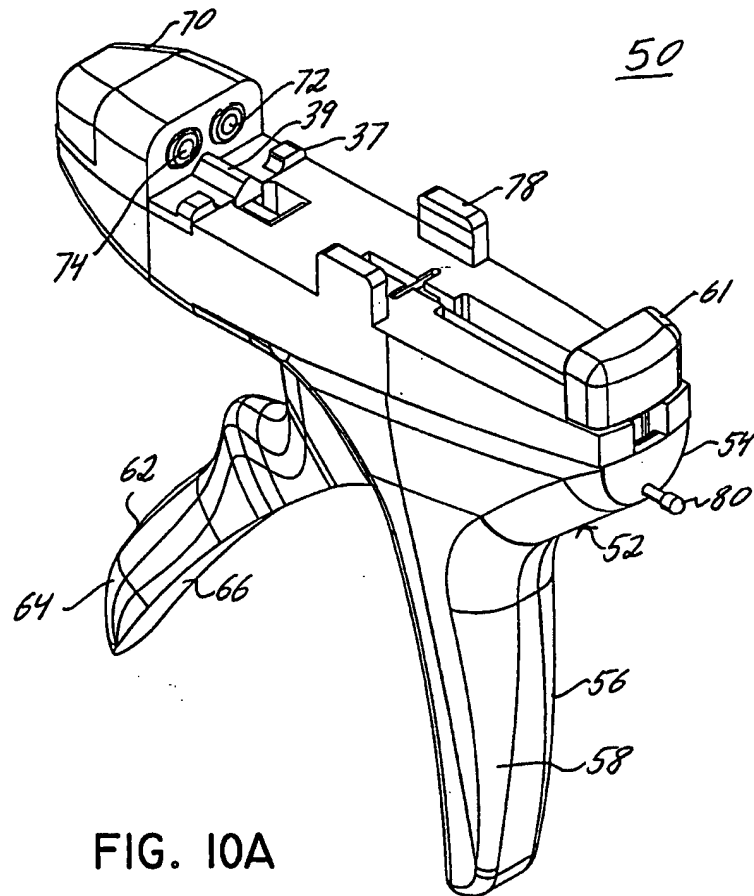


FIG. 10A

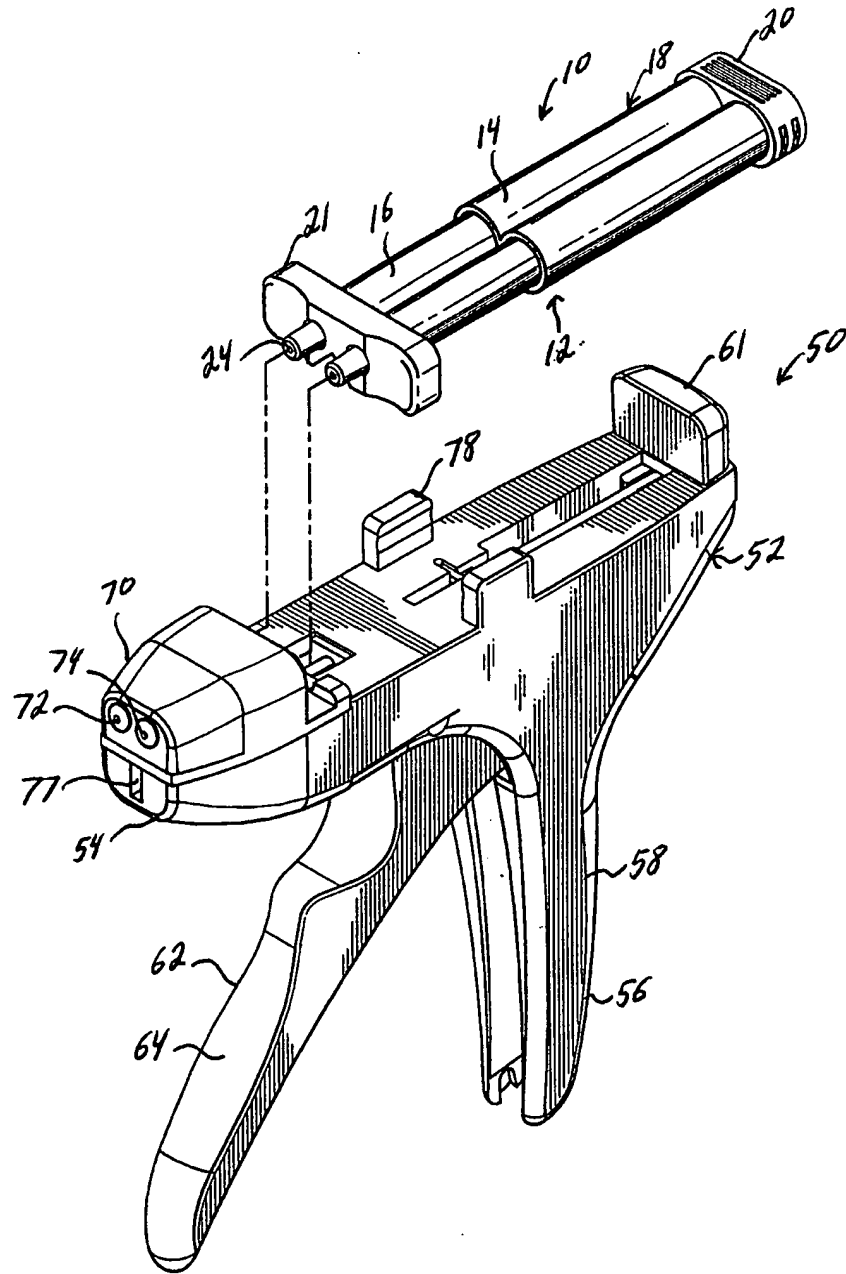
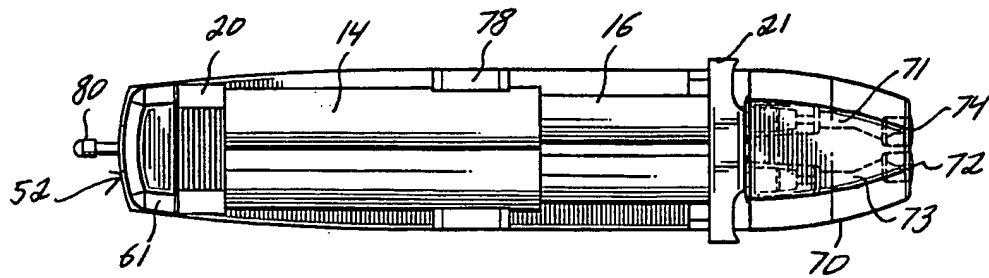
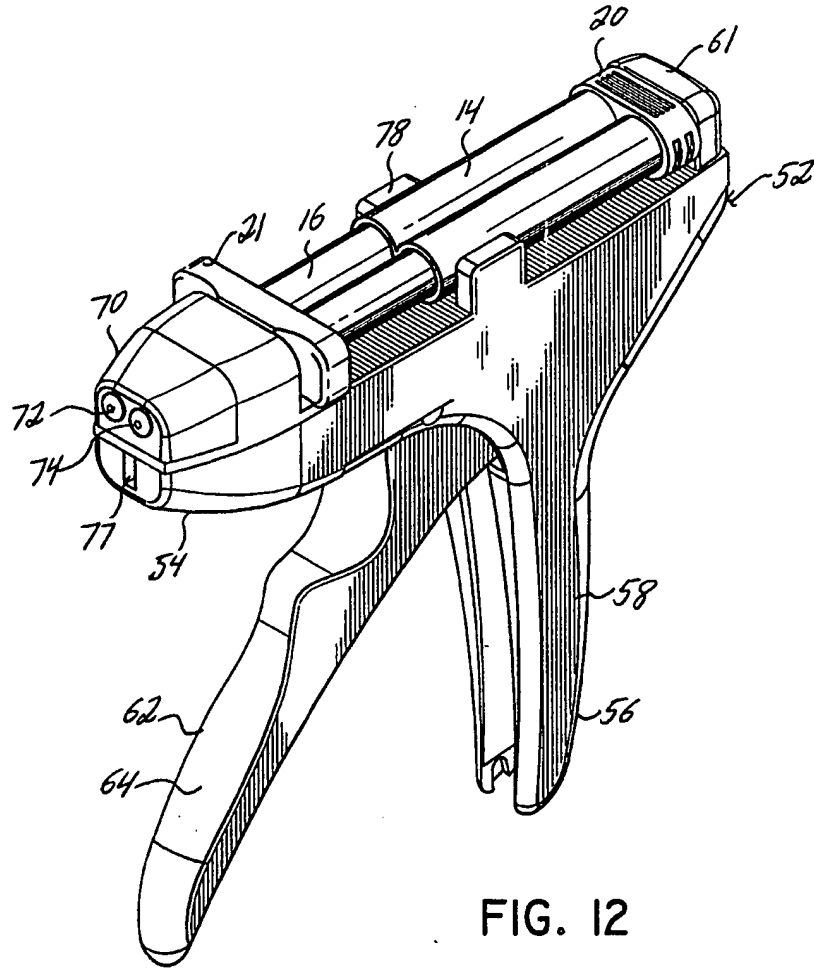


FIG. II



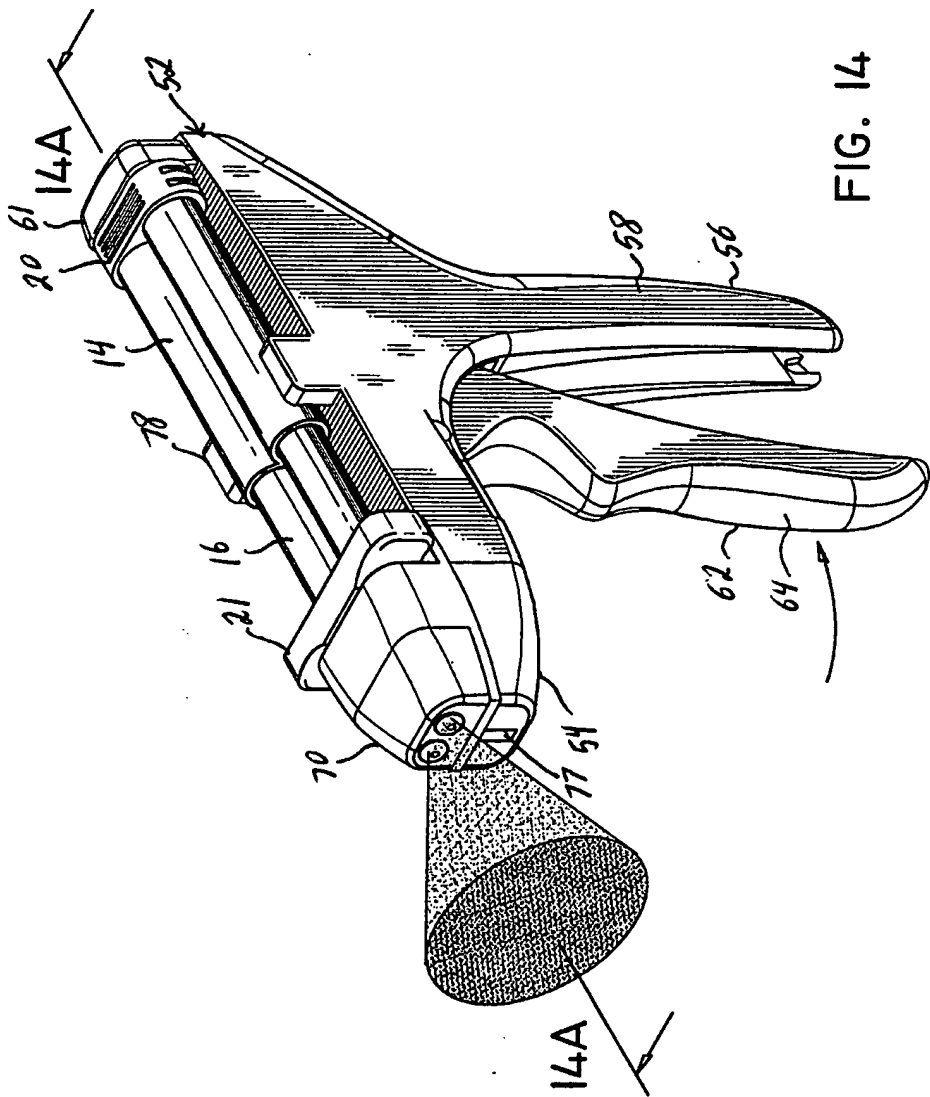


FIG. 14

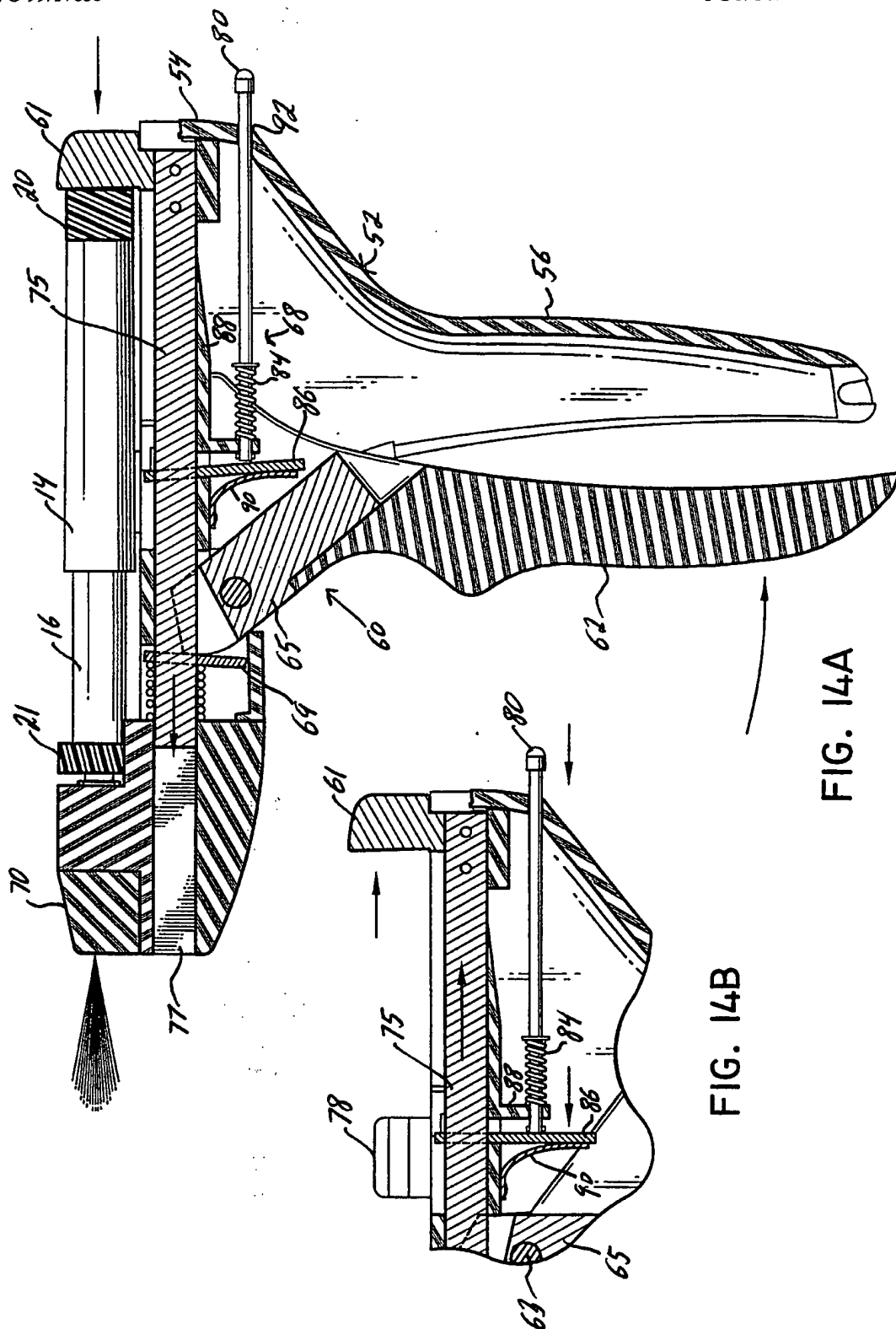
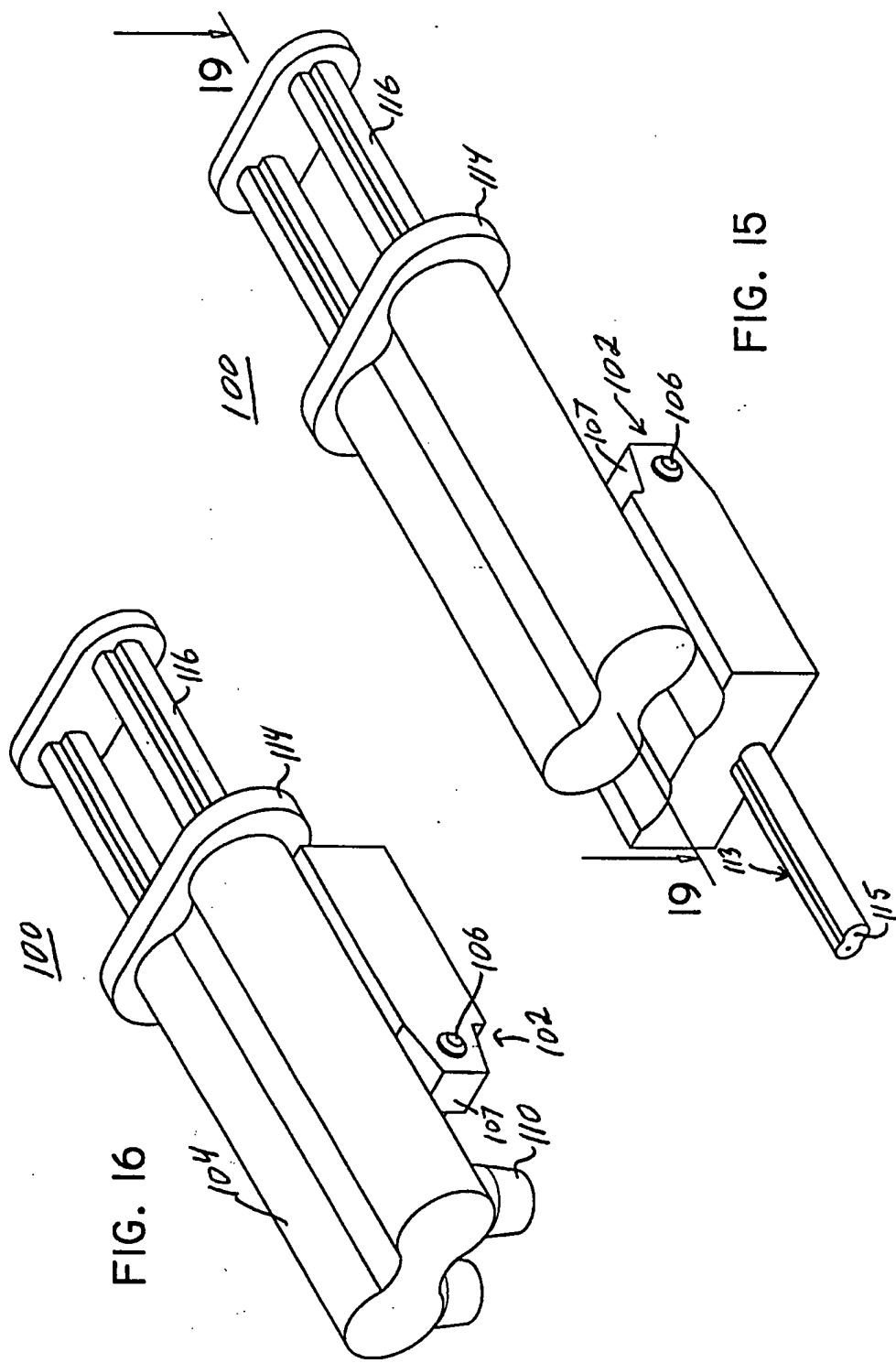
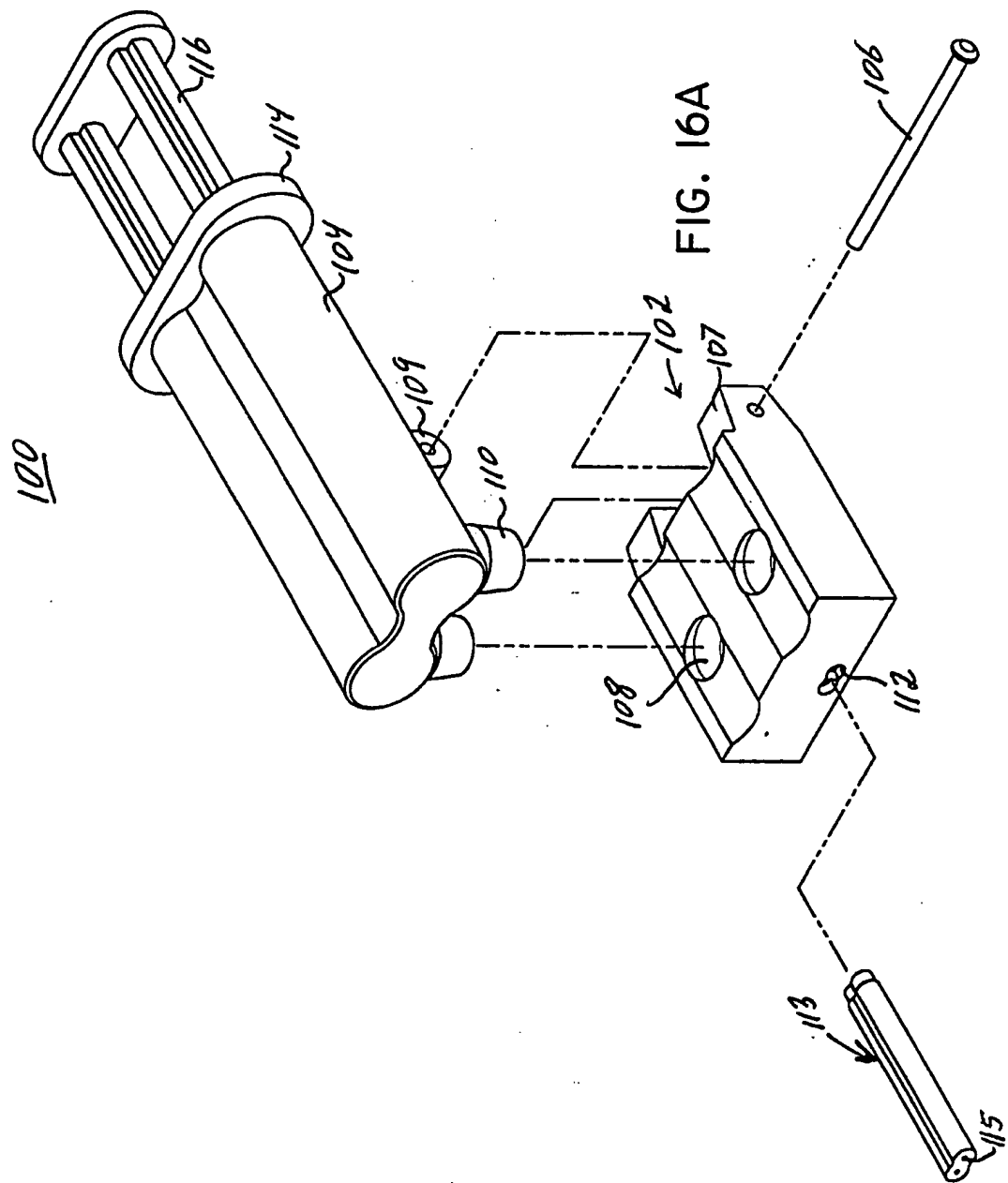


FIG. 14A

FIG. 14B





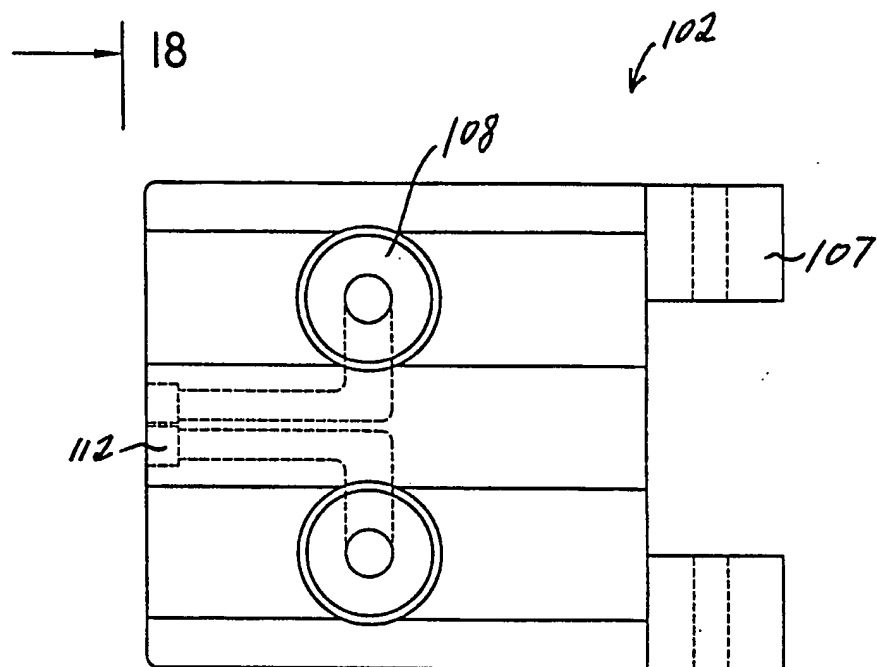


FIG. 17

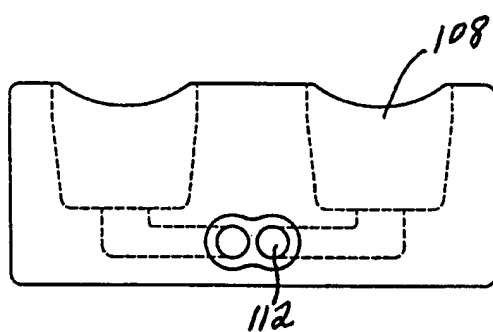


FIG. 18

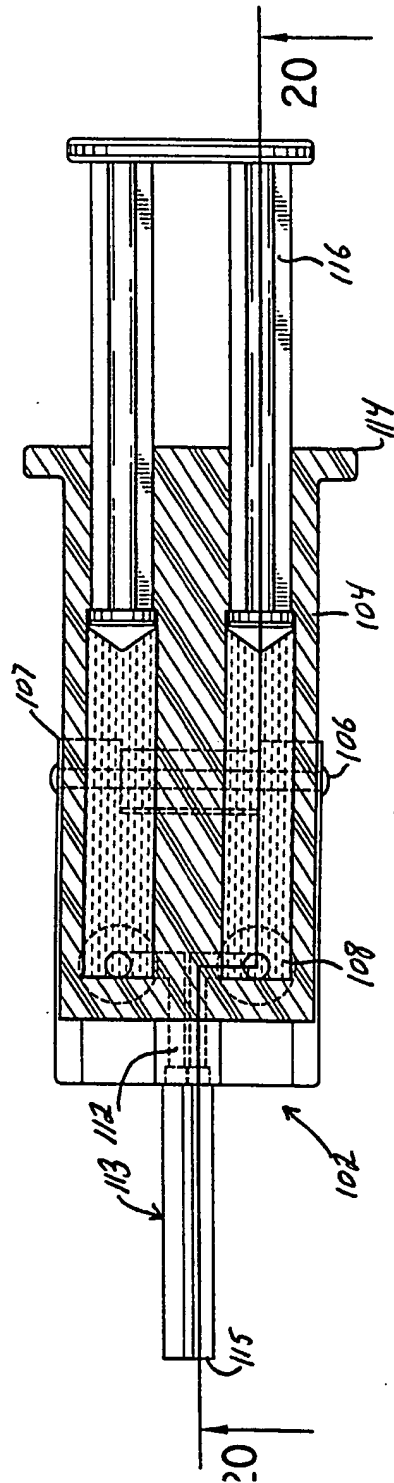


FIG. 19

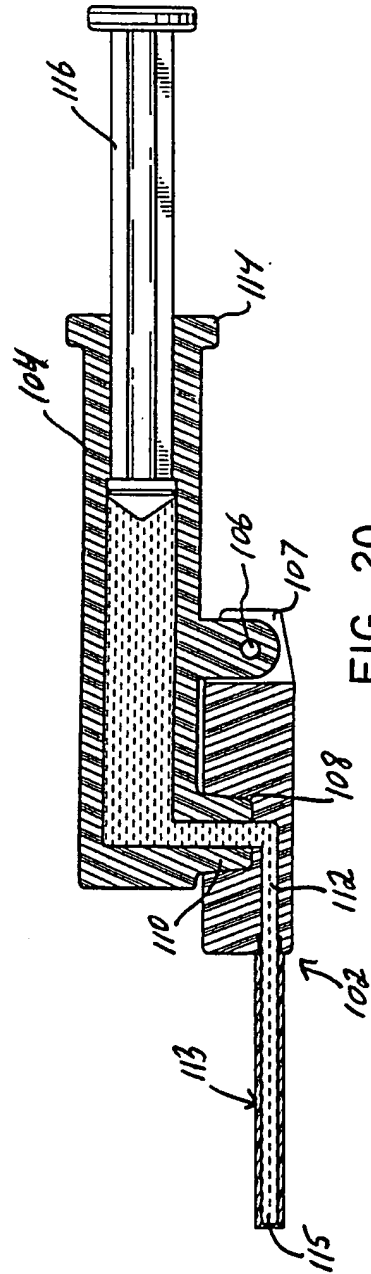


FIG. 20

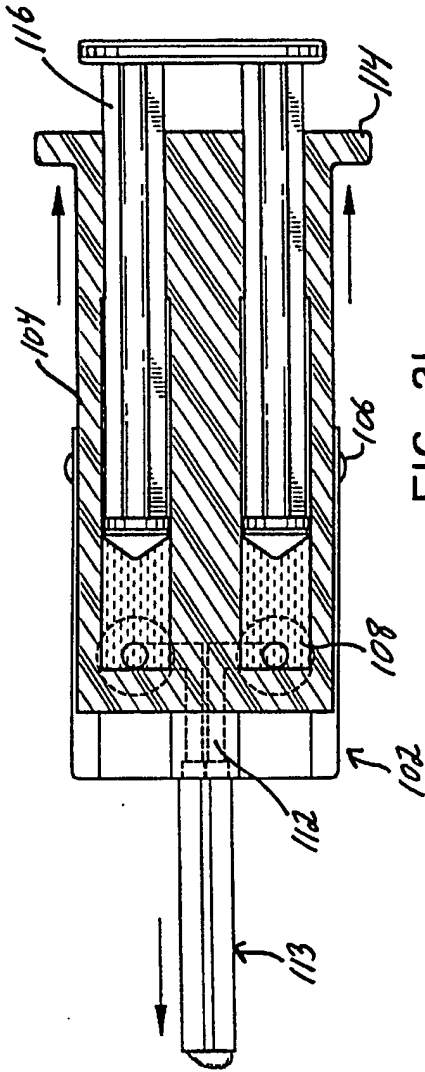


FIG. 21

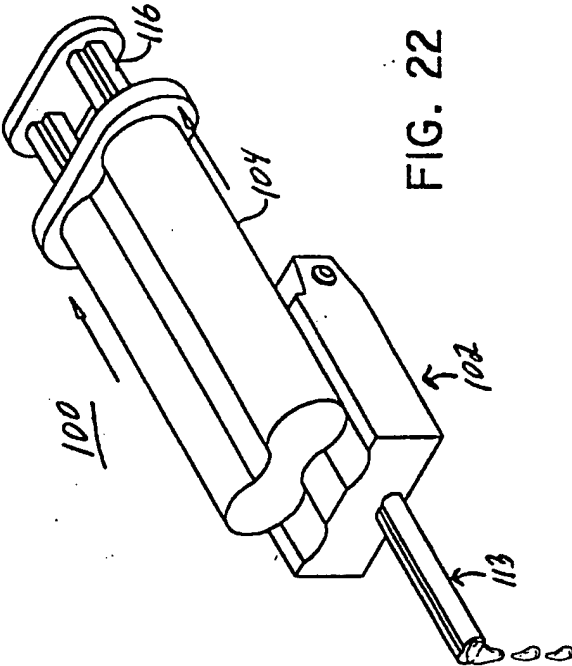


FIG. 22

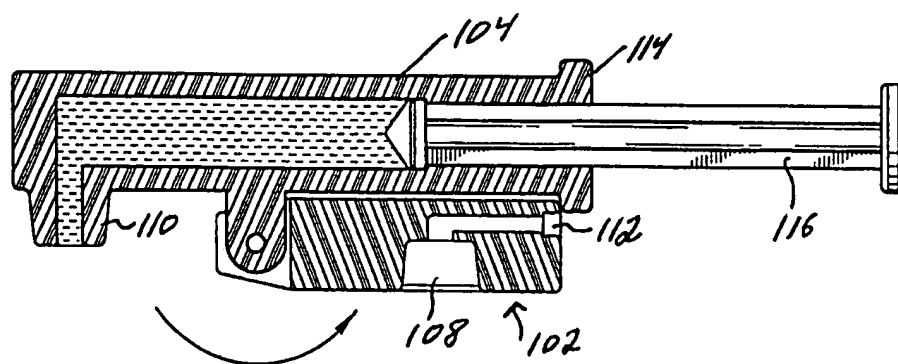


FIG. 23

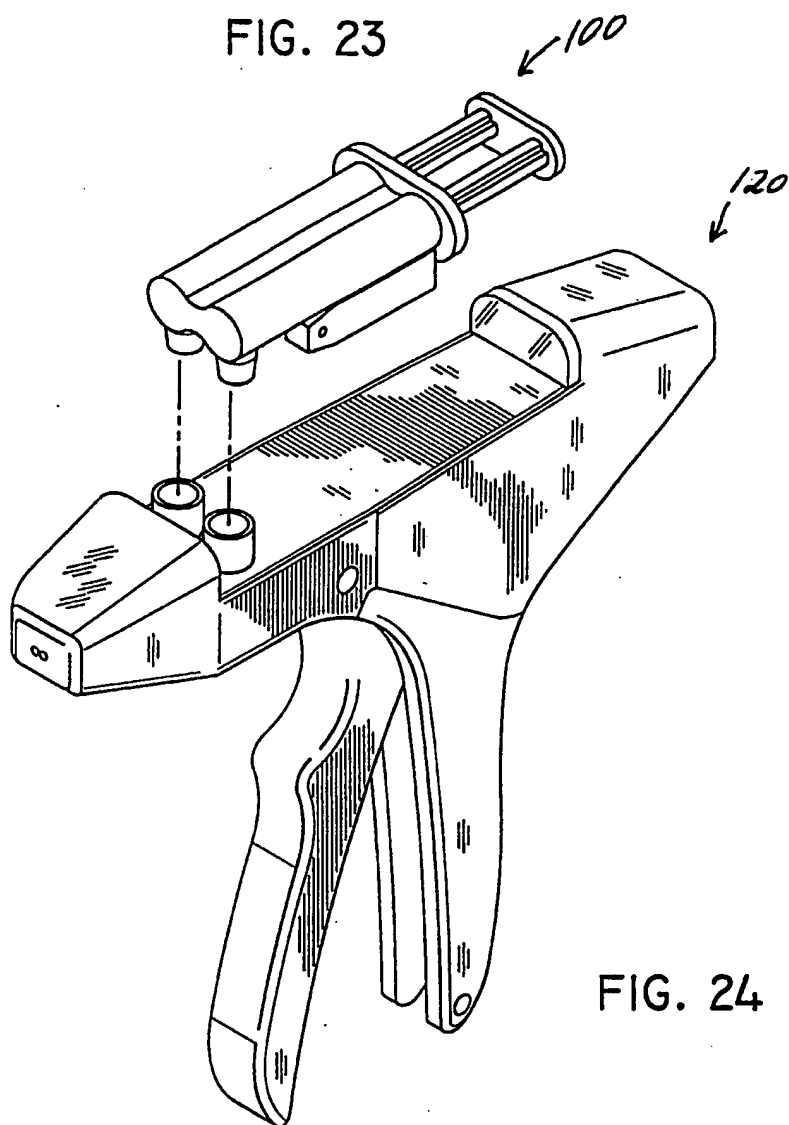
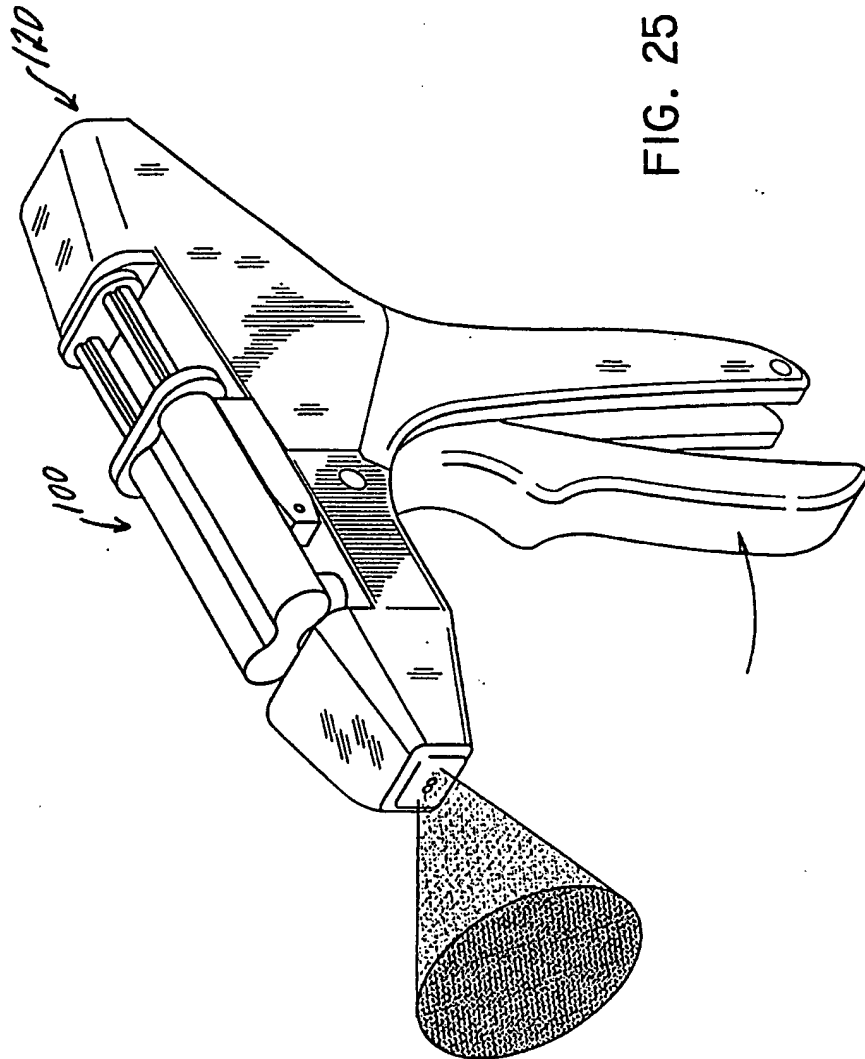


FIG. 24



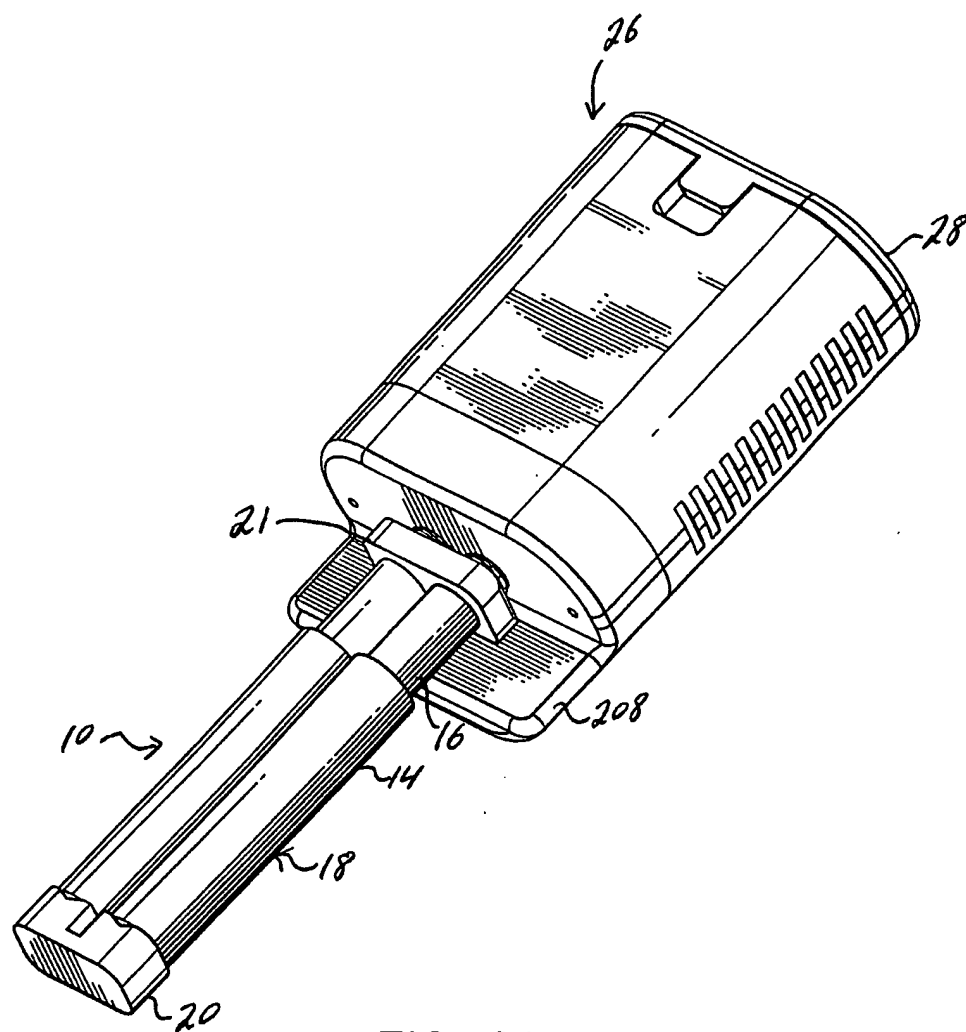


FIG. 26

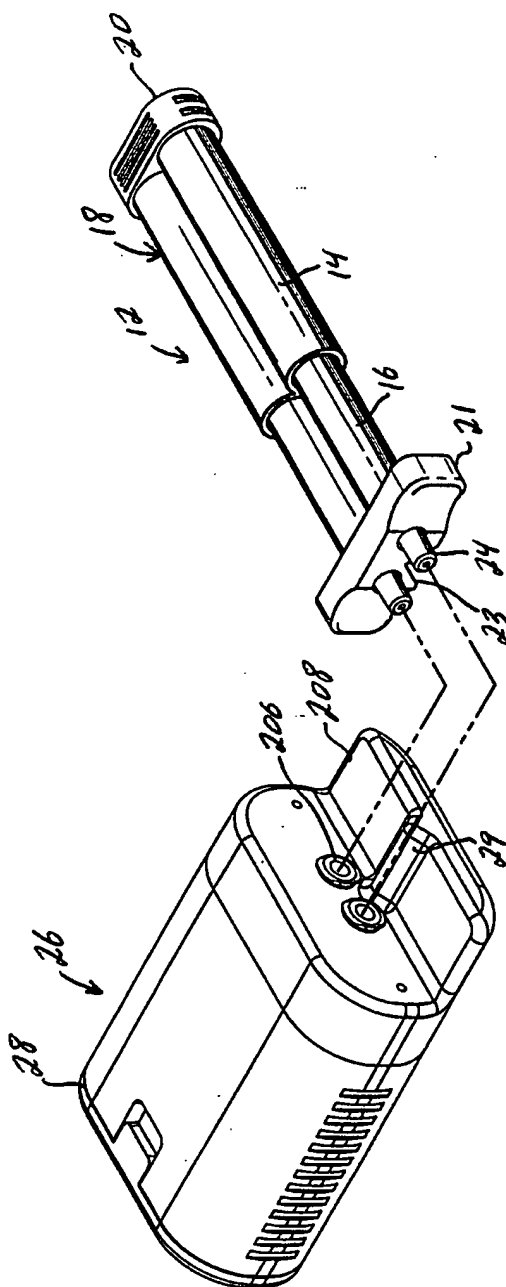
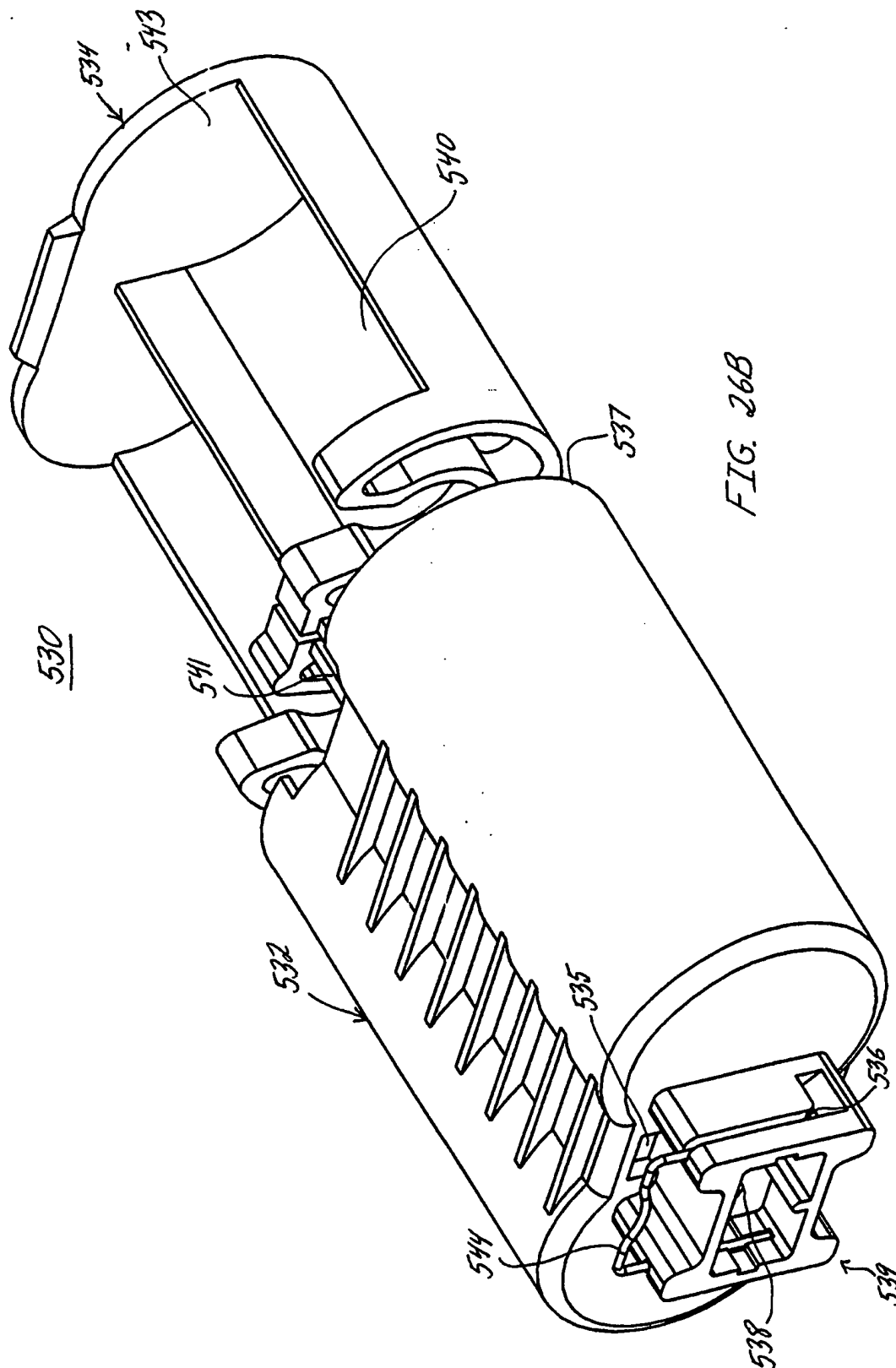


FIG. 26A



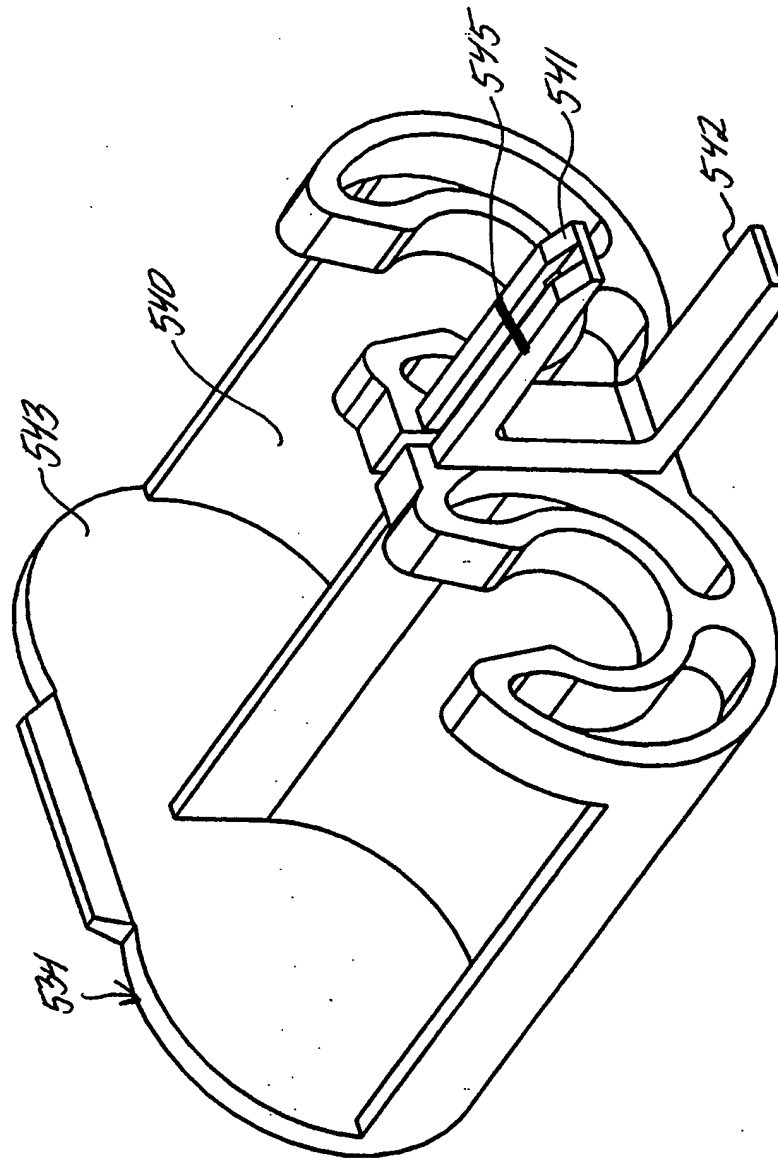
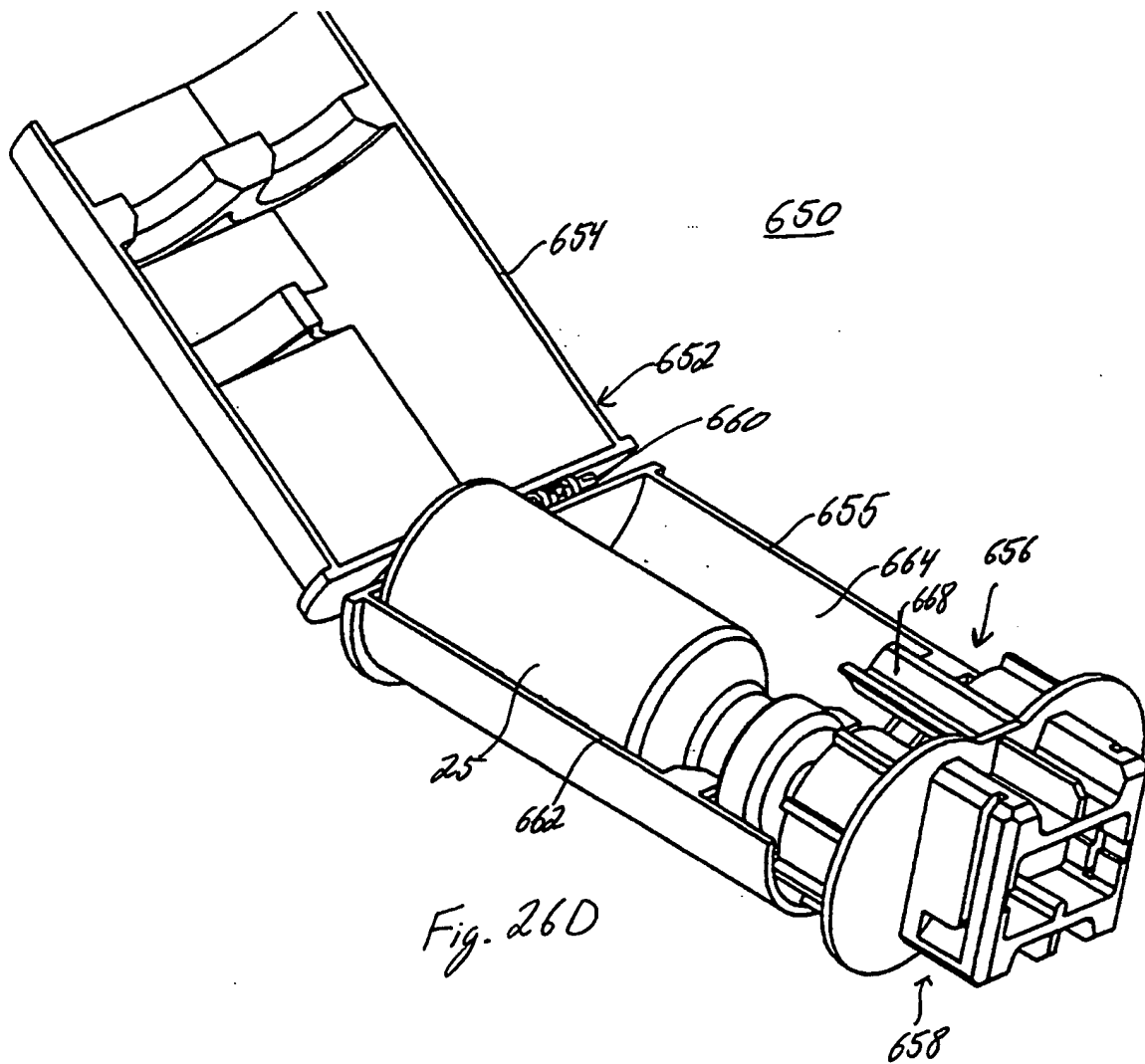
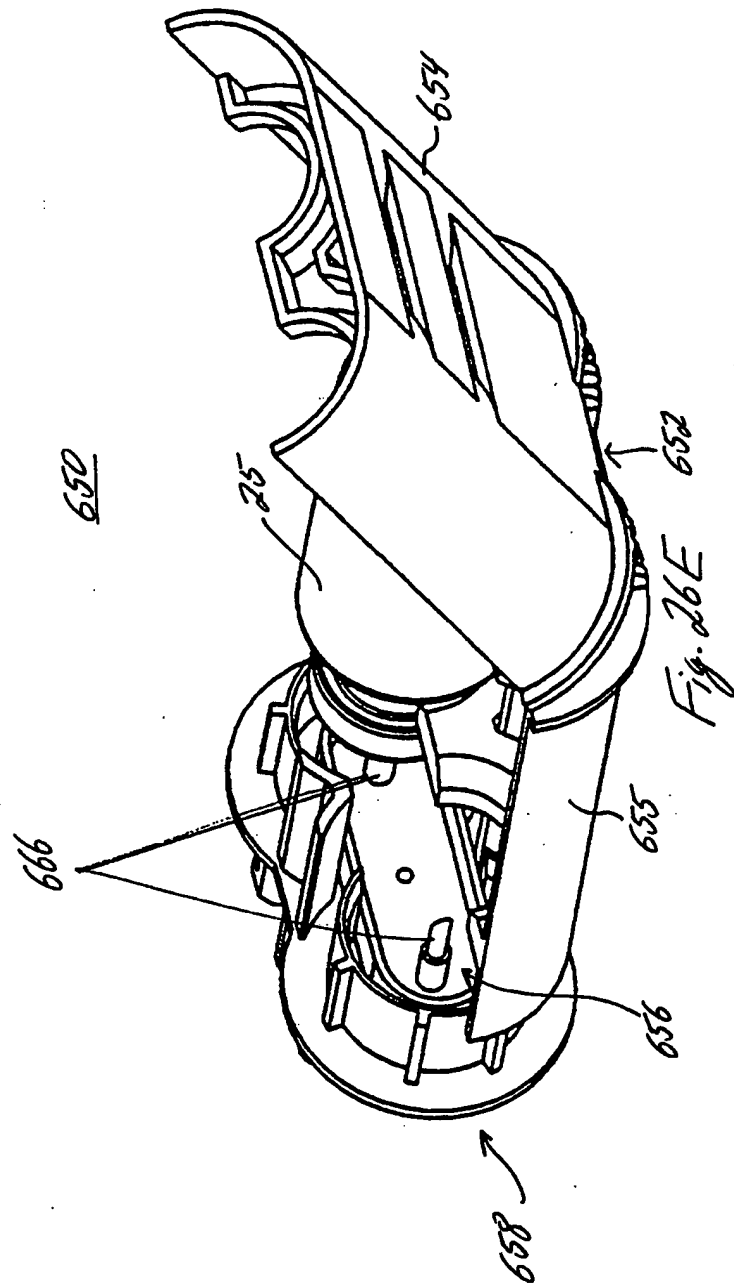


FIG. 26C





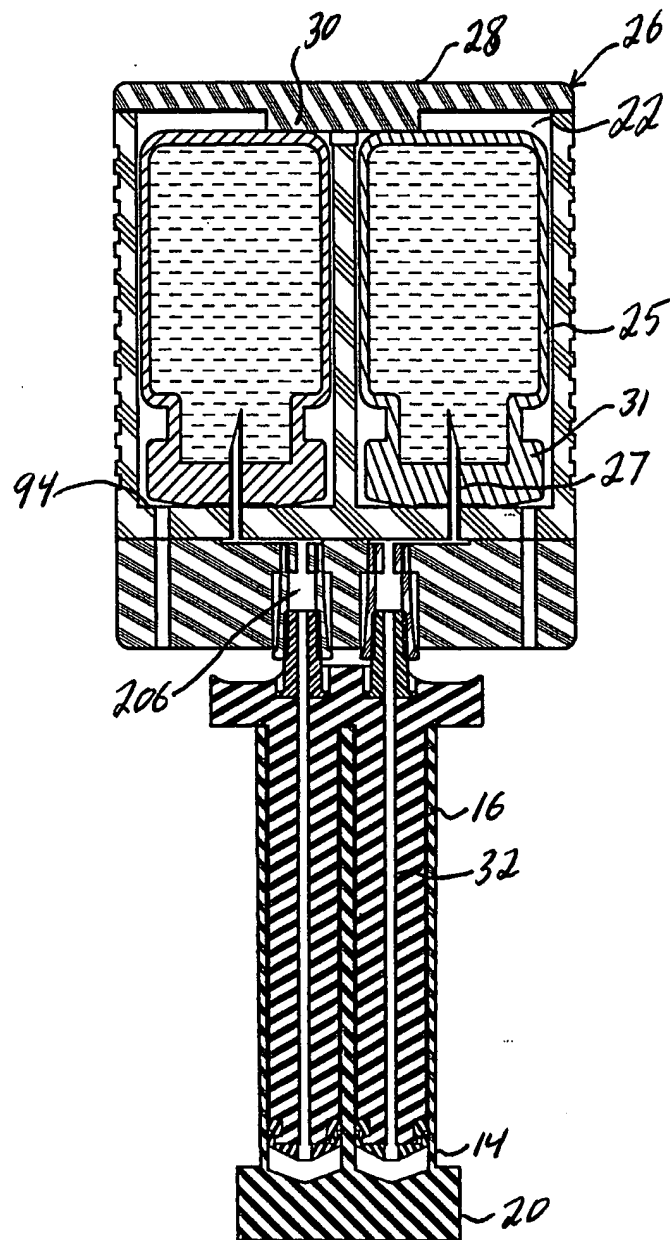


FIG. 27

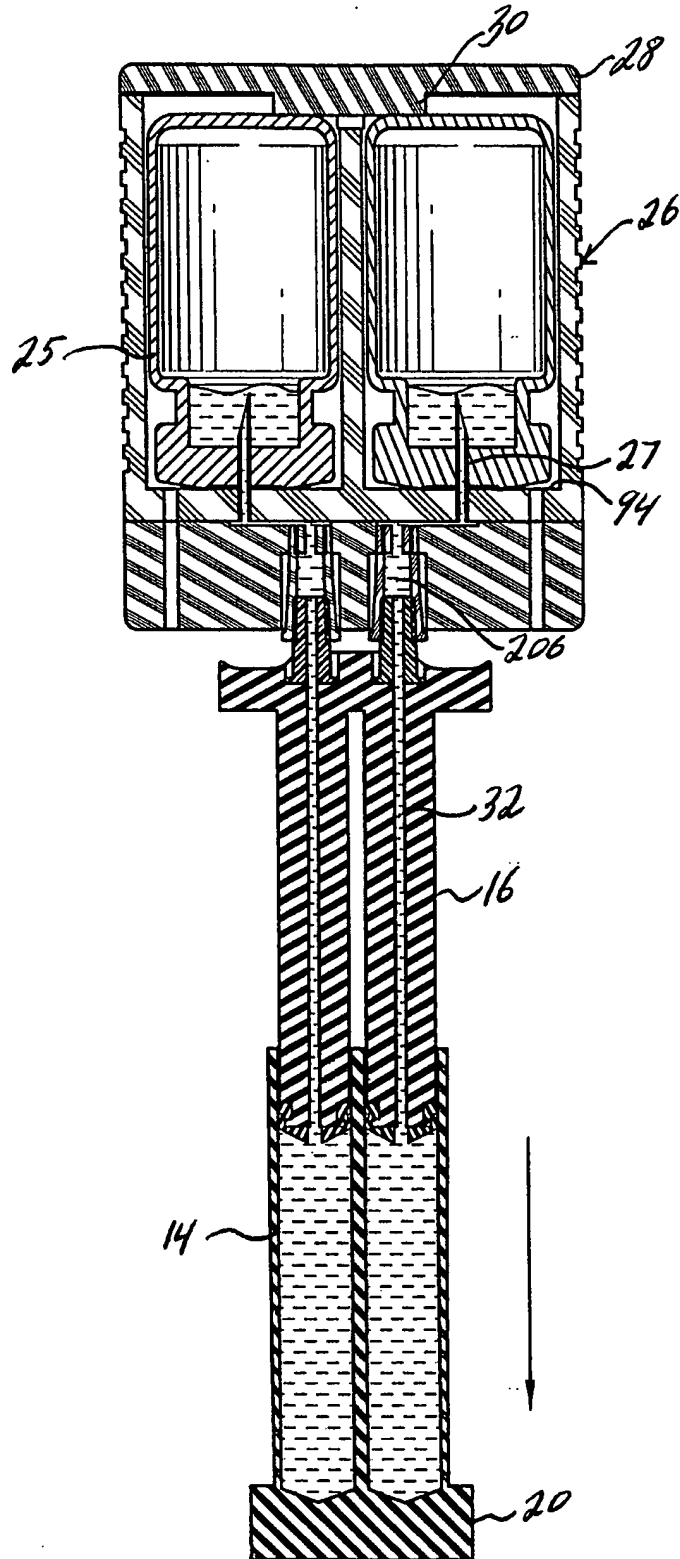
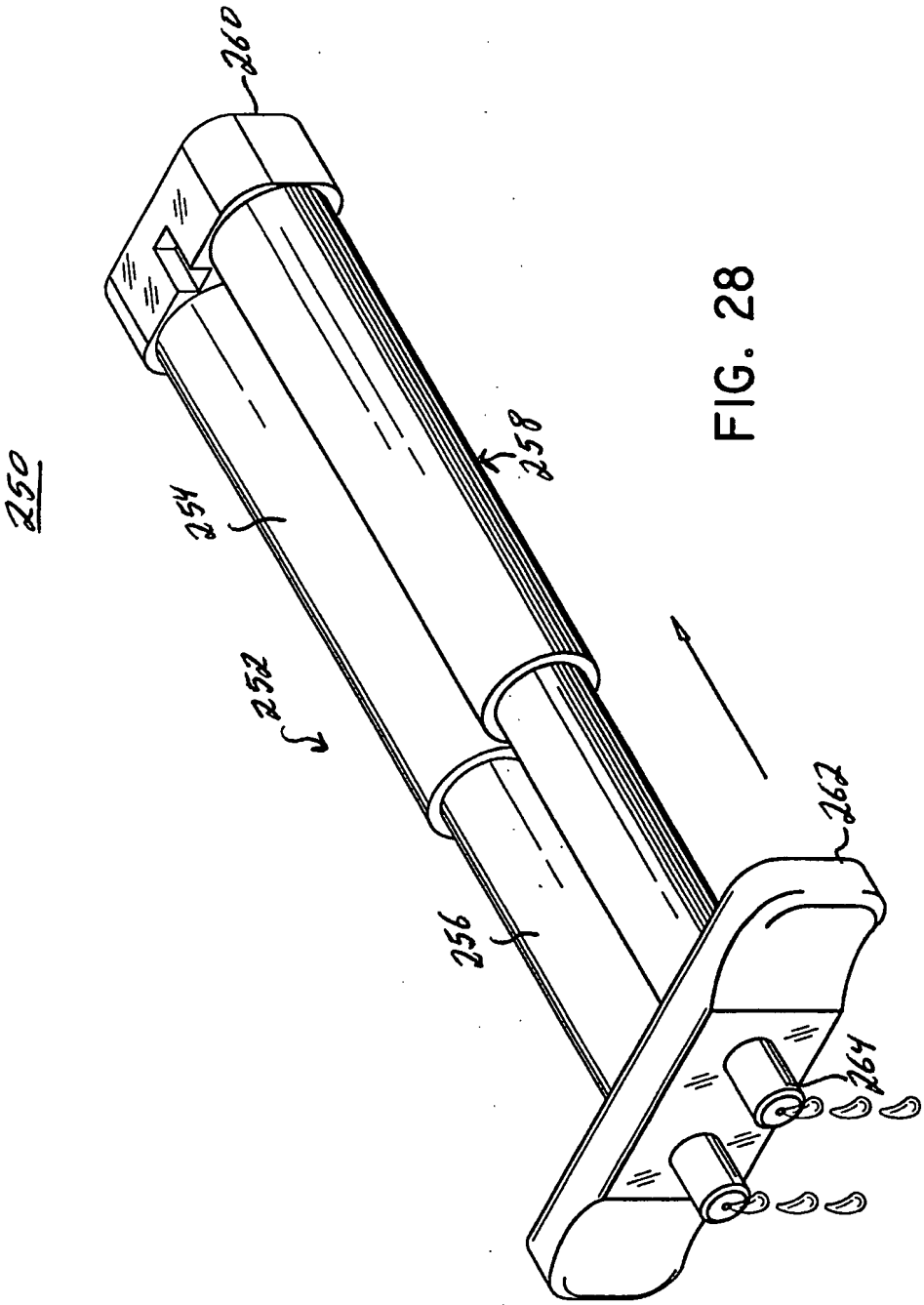
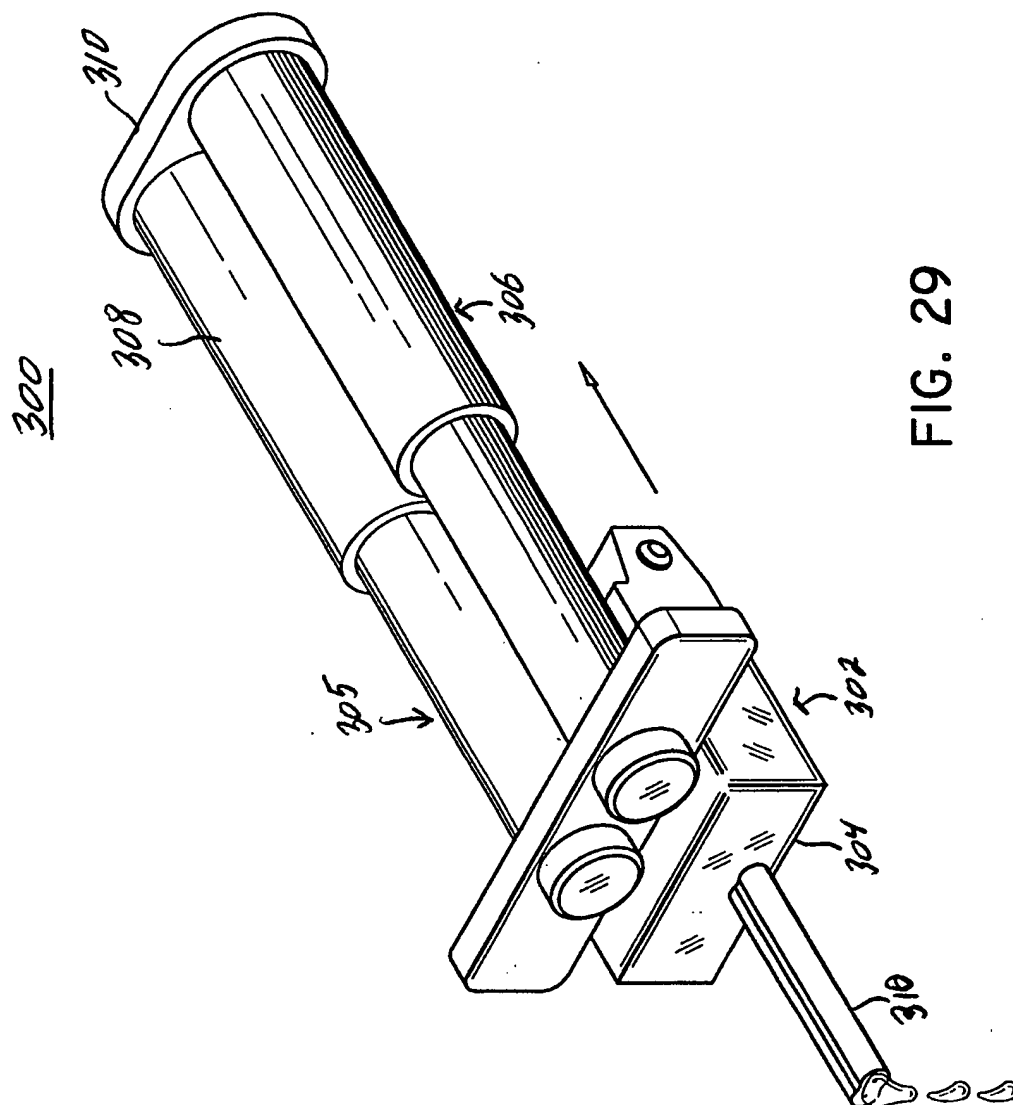


FIG. 27A





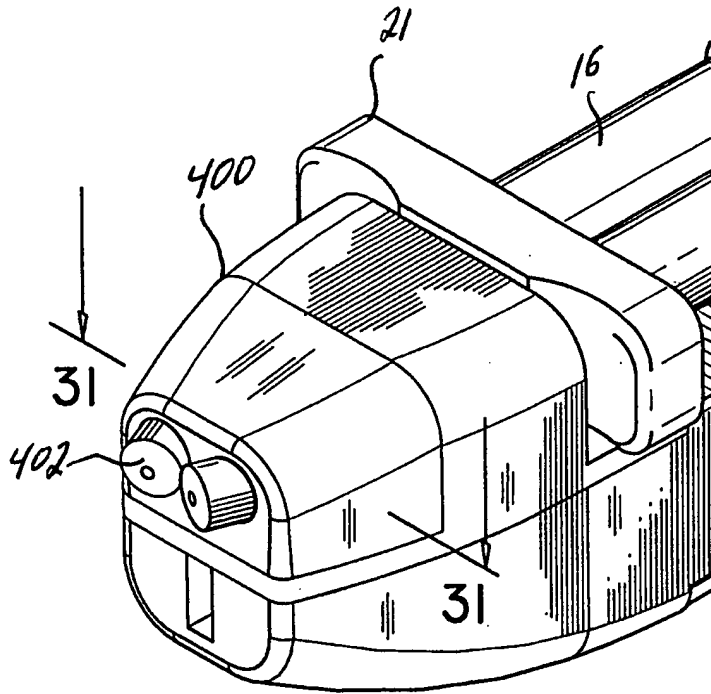


FIG. 30

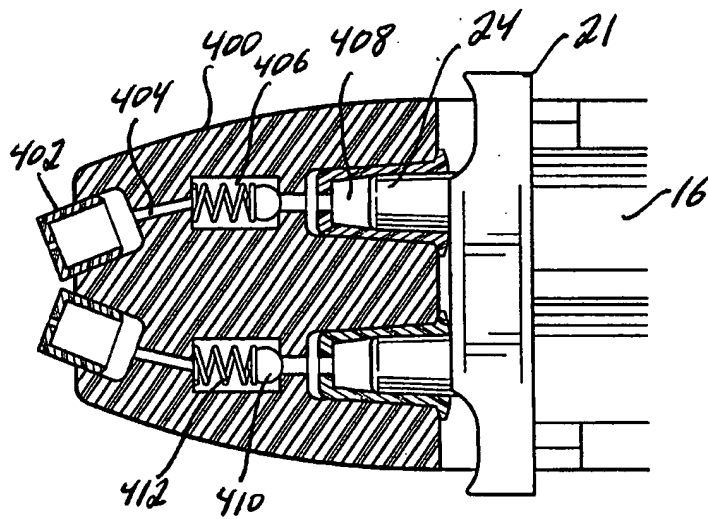


FIG. 31

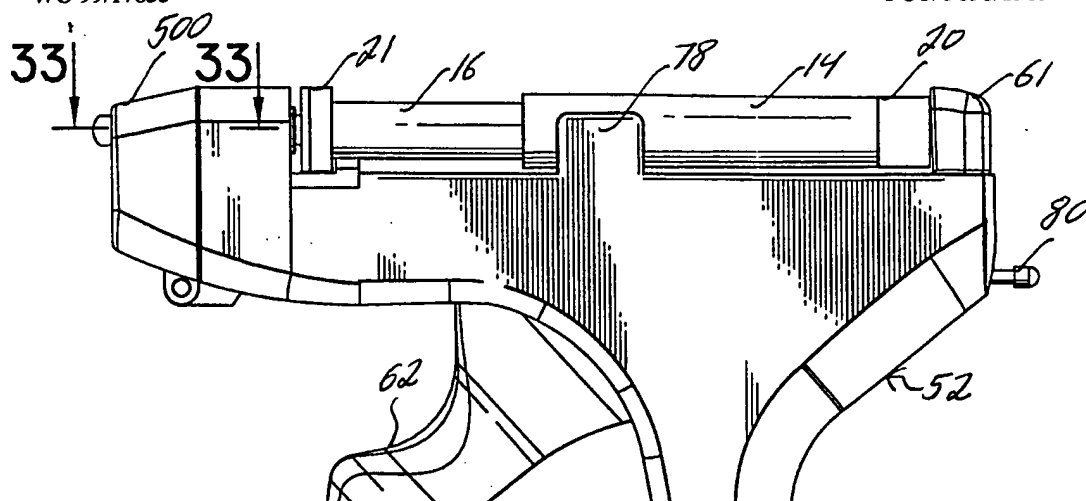


FIG. 32

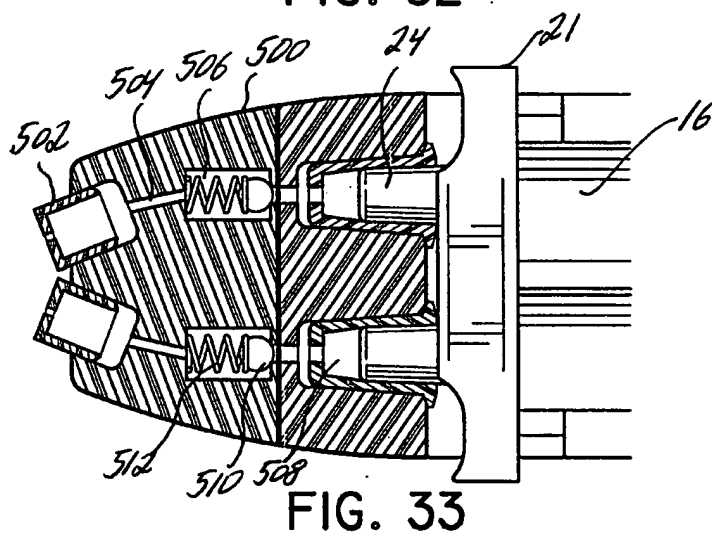


FIG. 33

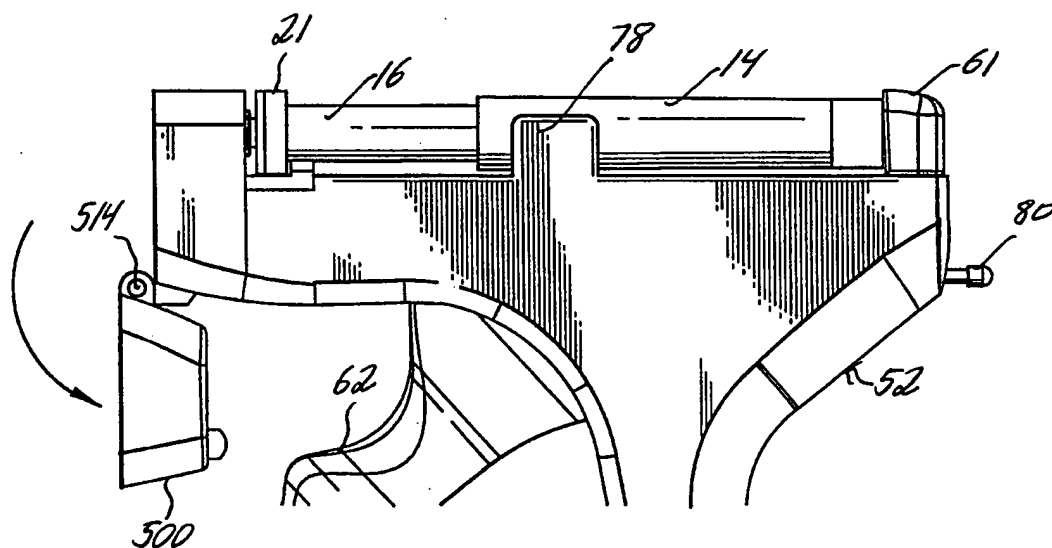


FIG. 34

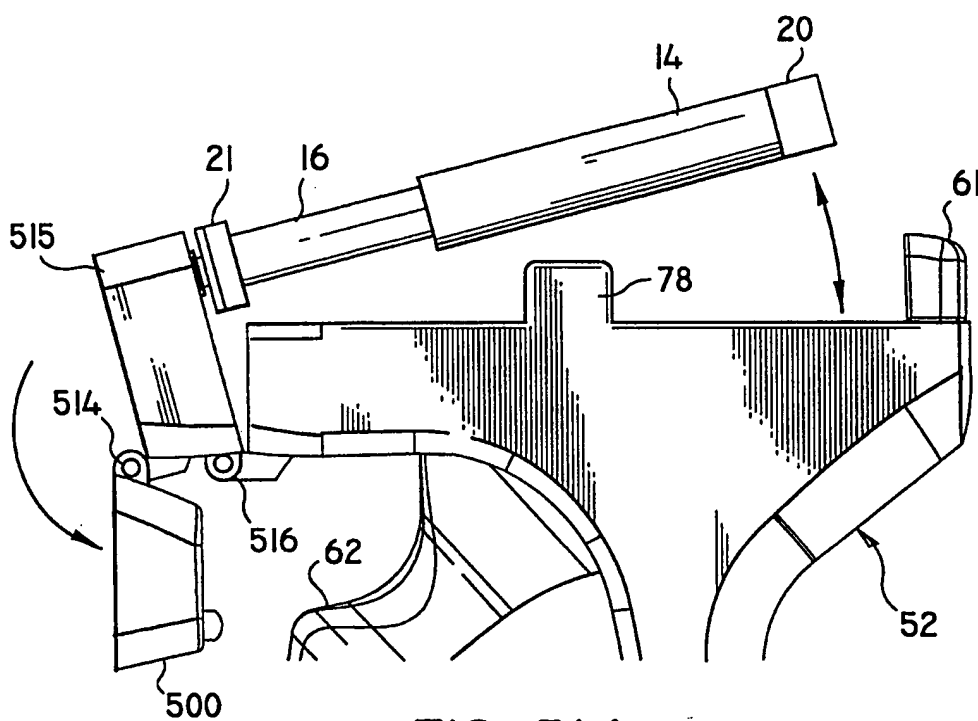


FIG. 34A

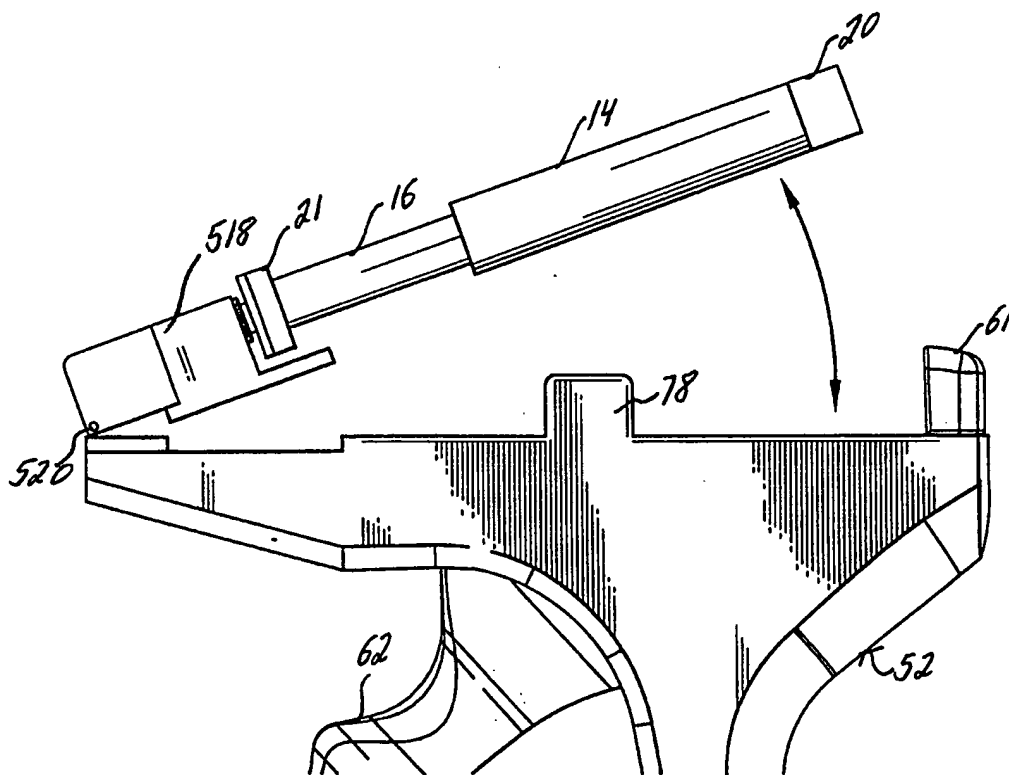
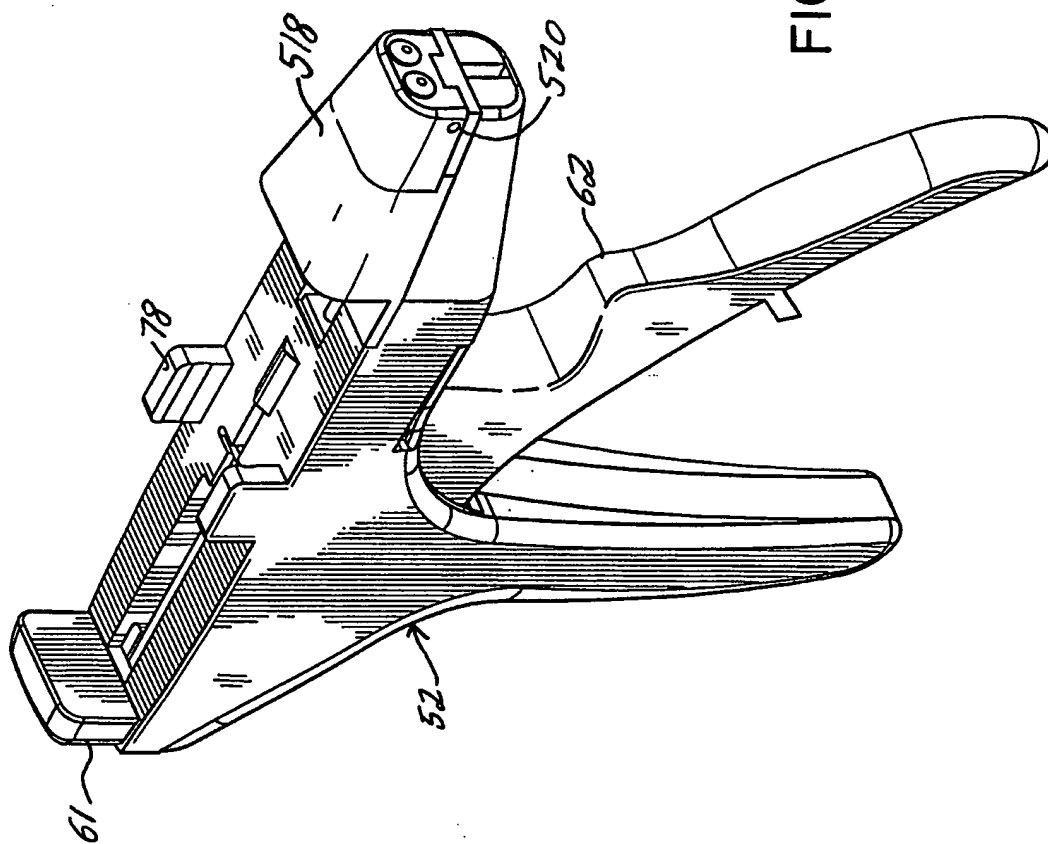
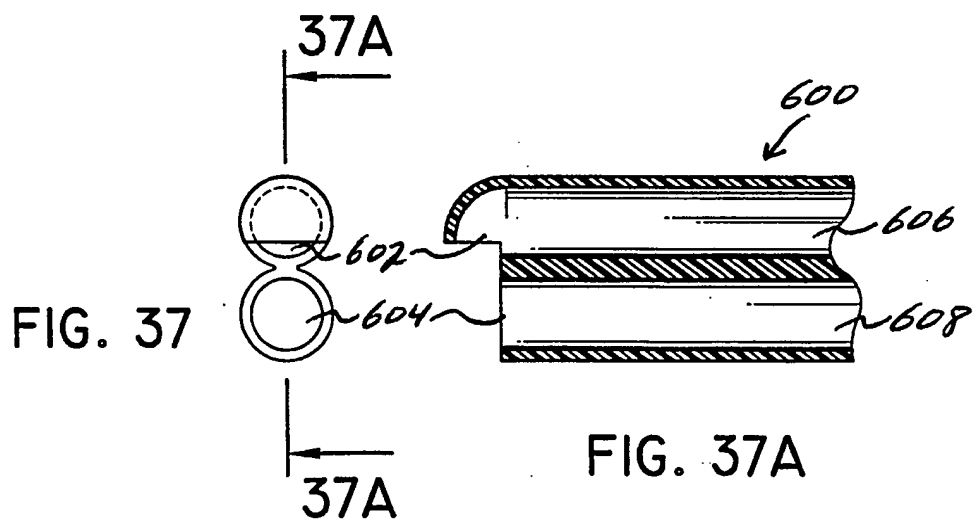
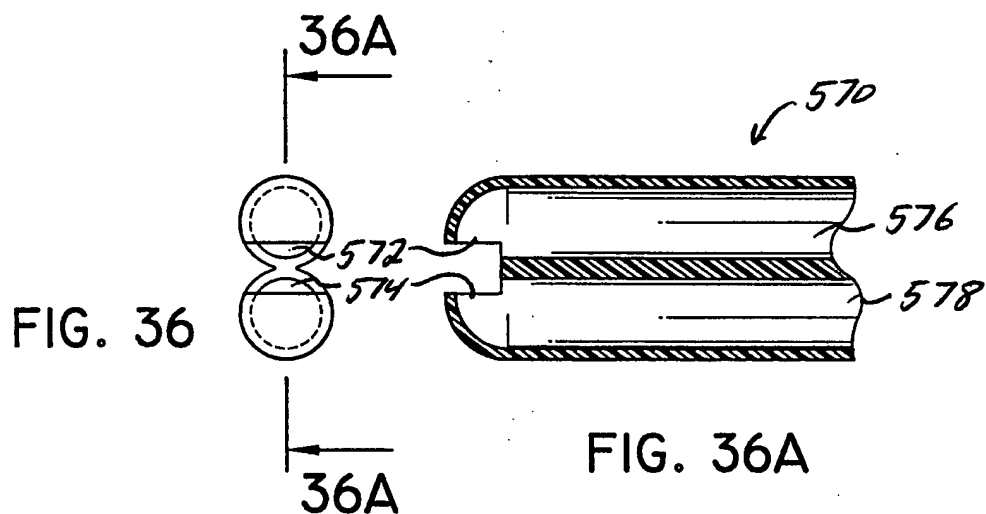
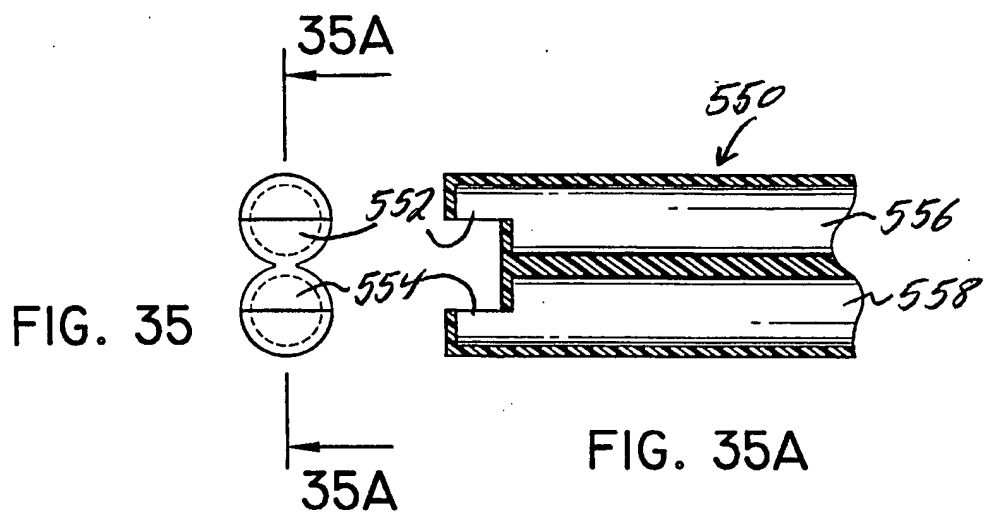
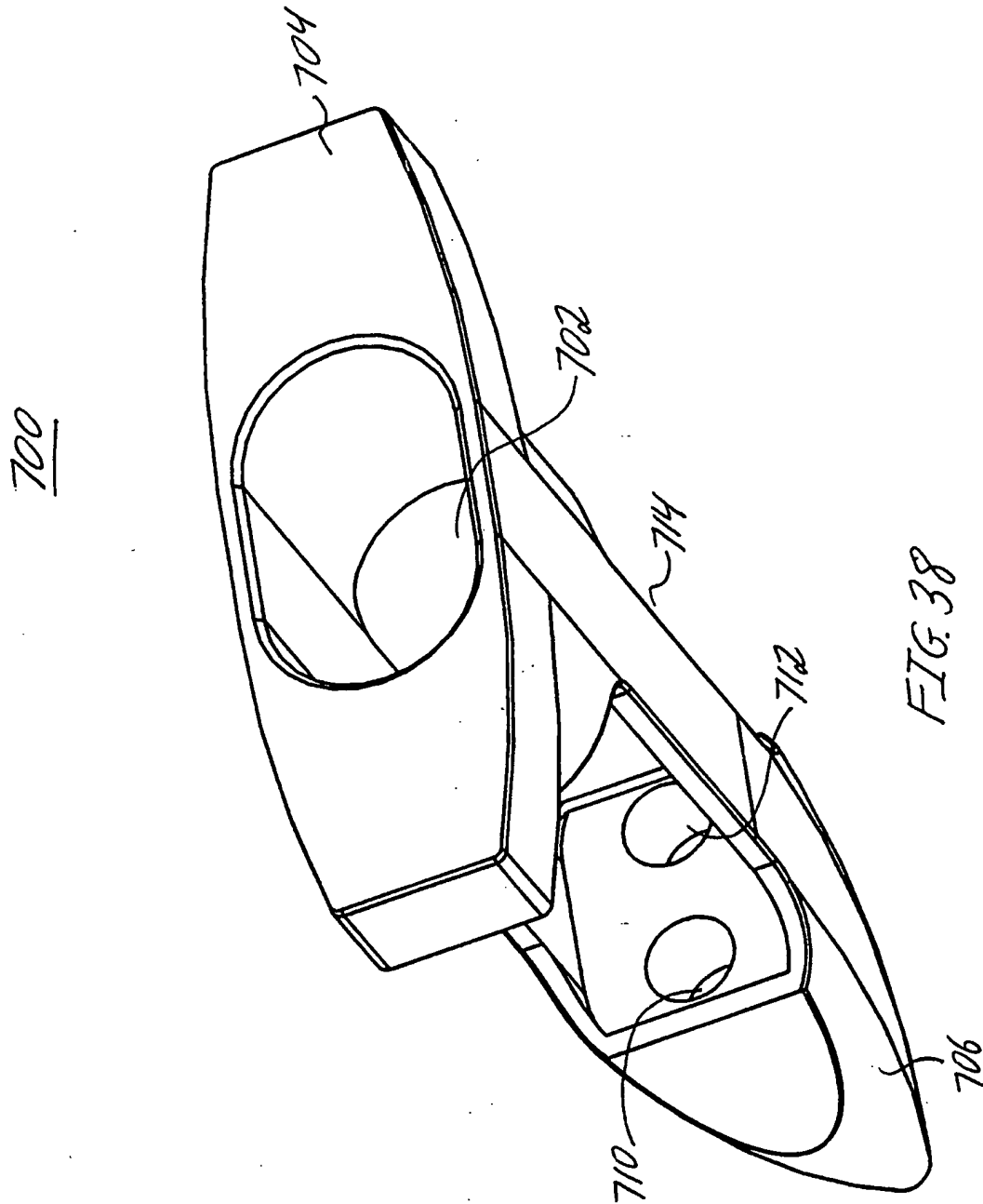


FIG. 34B

FIG. 34C







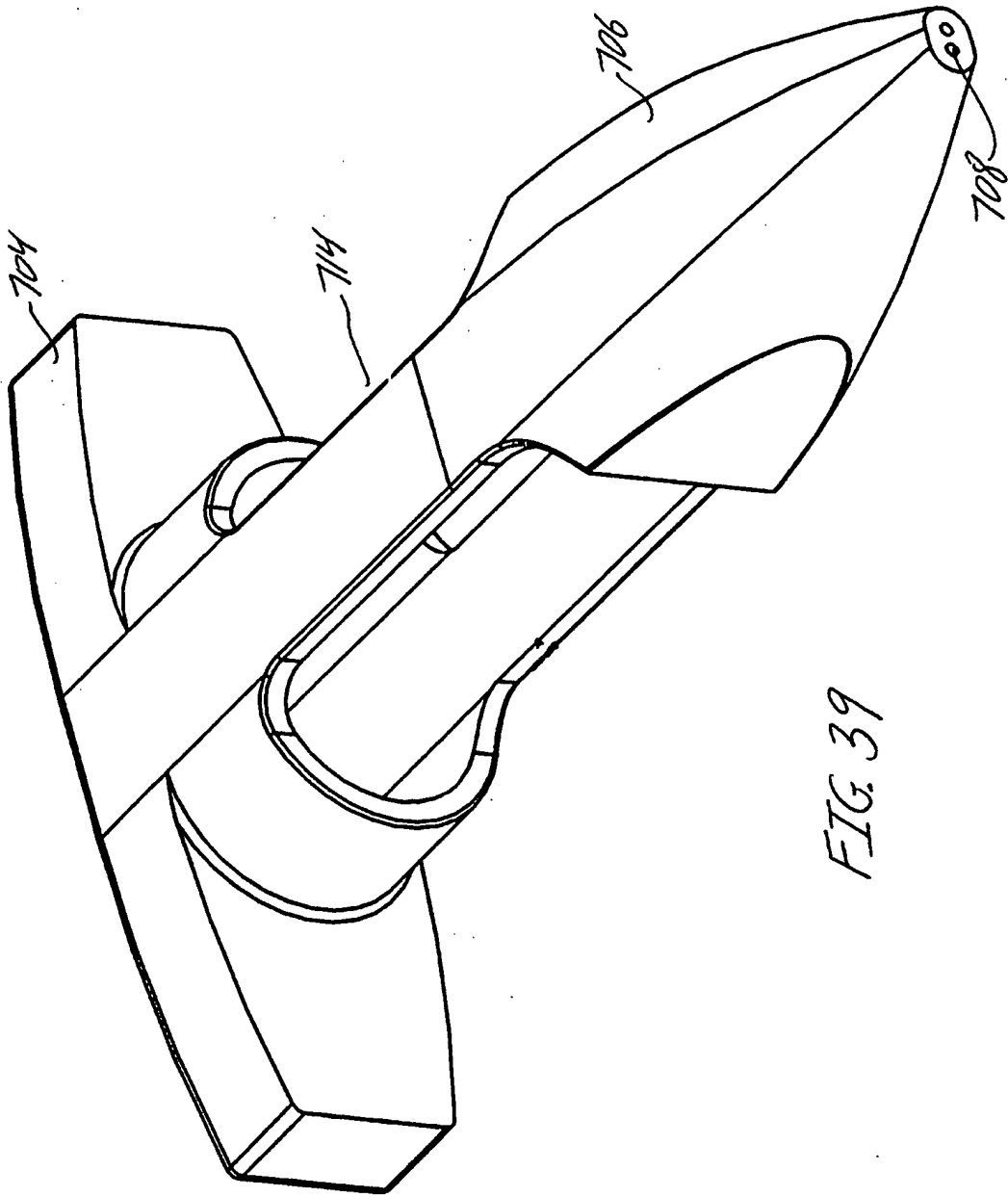


FIG. 39

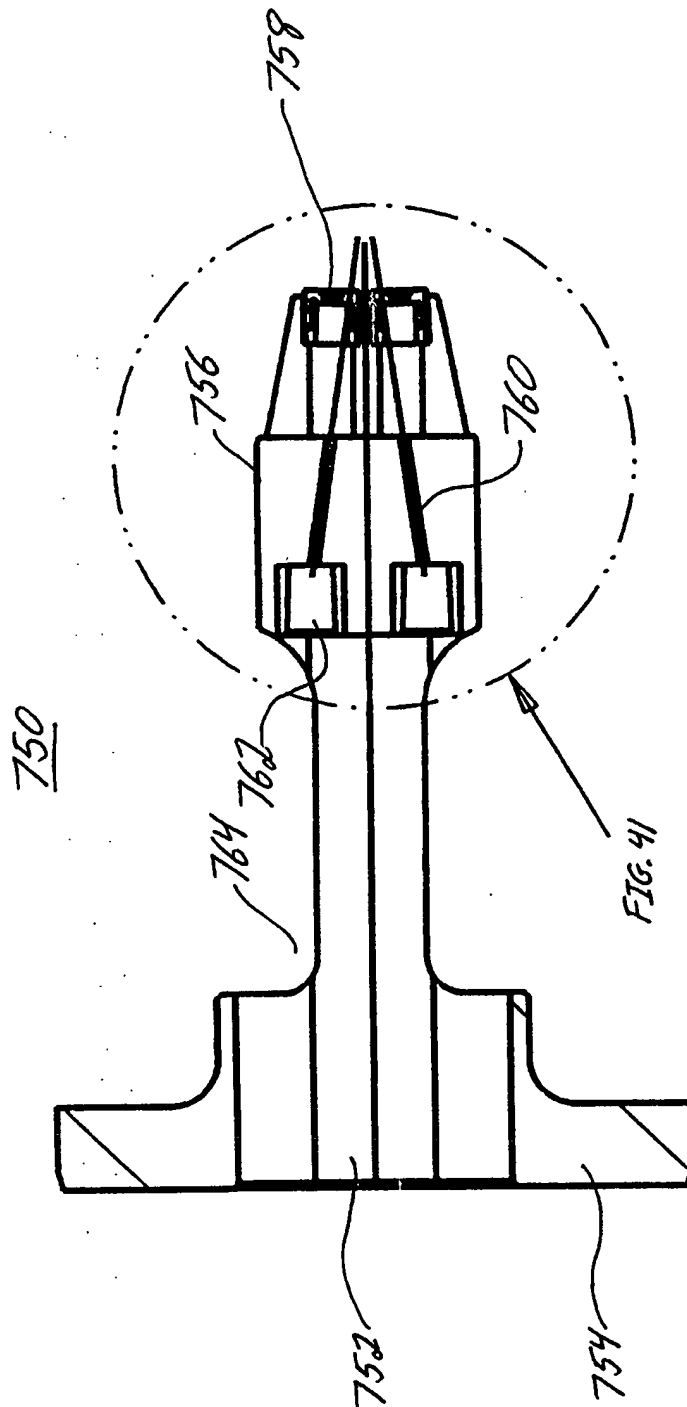


FIG. 40

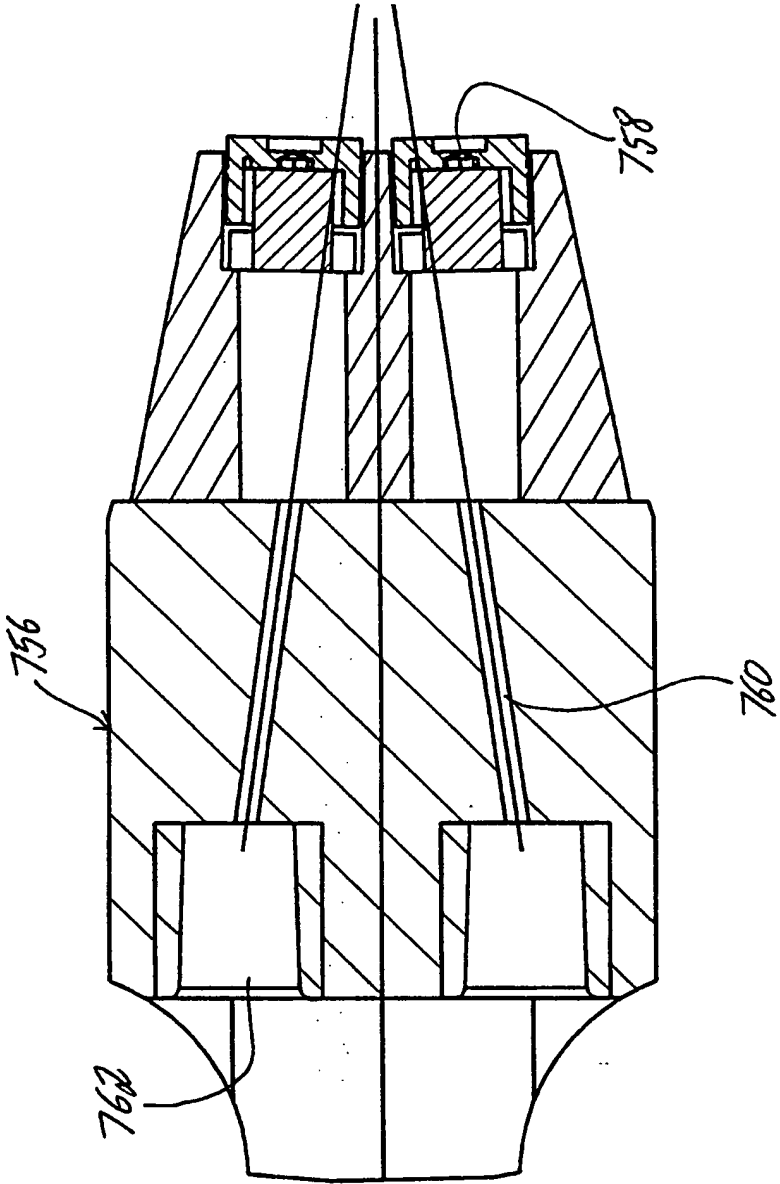
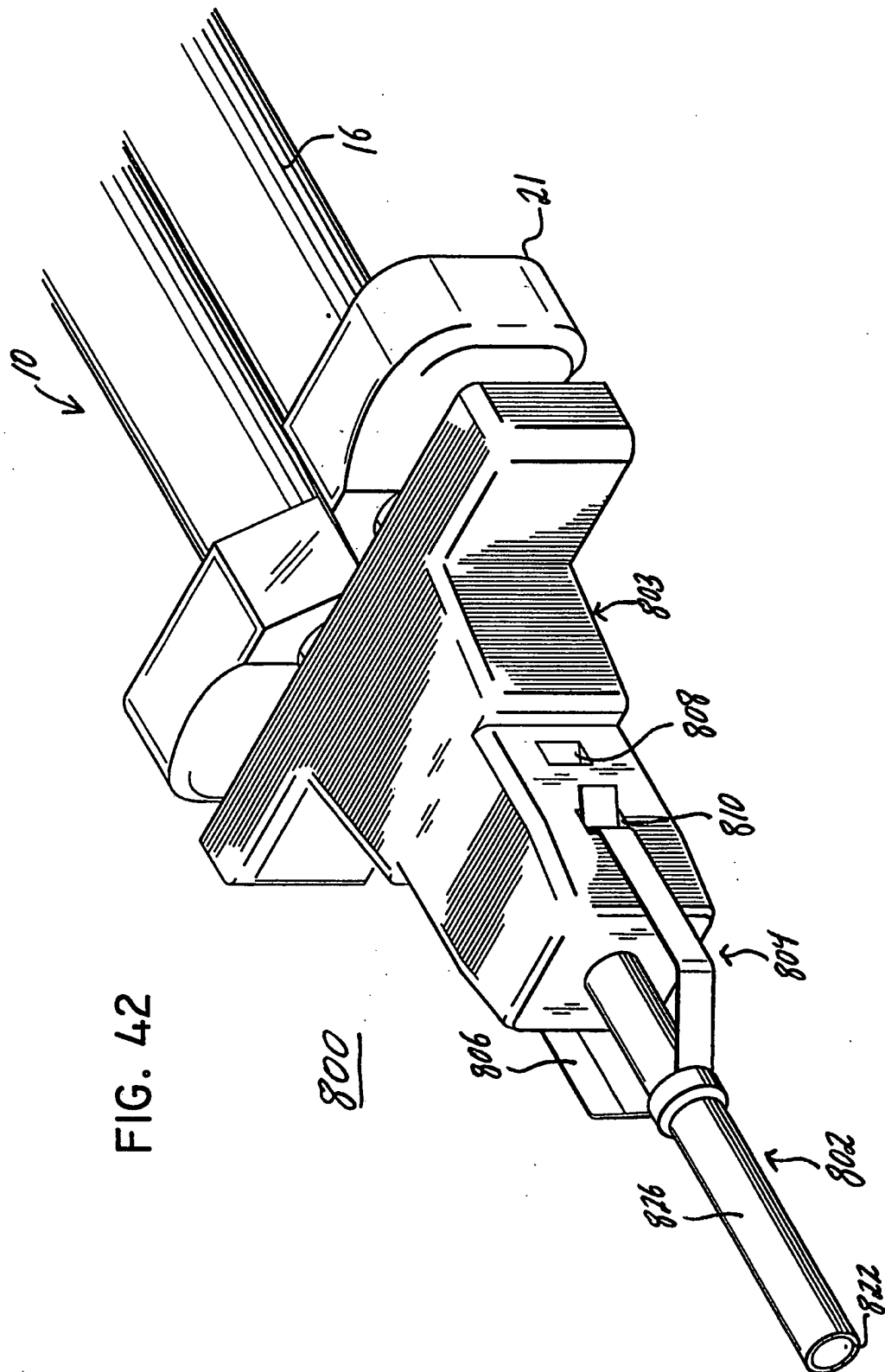


FIG. 41



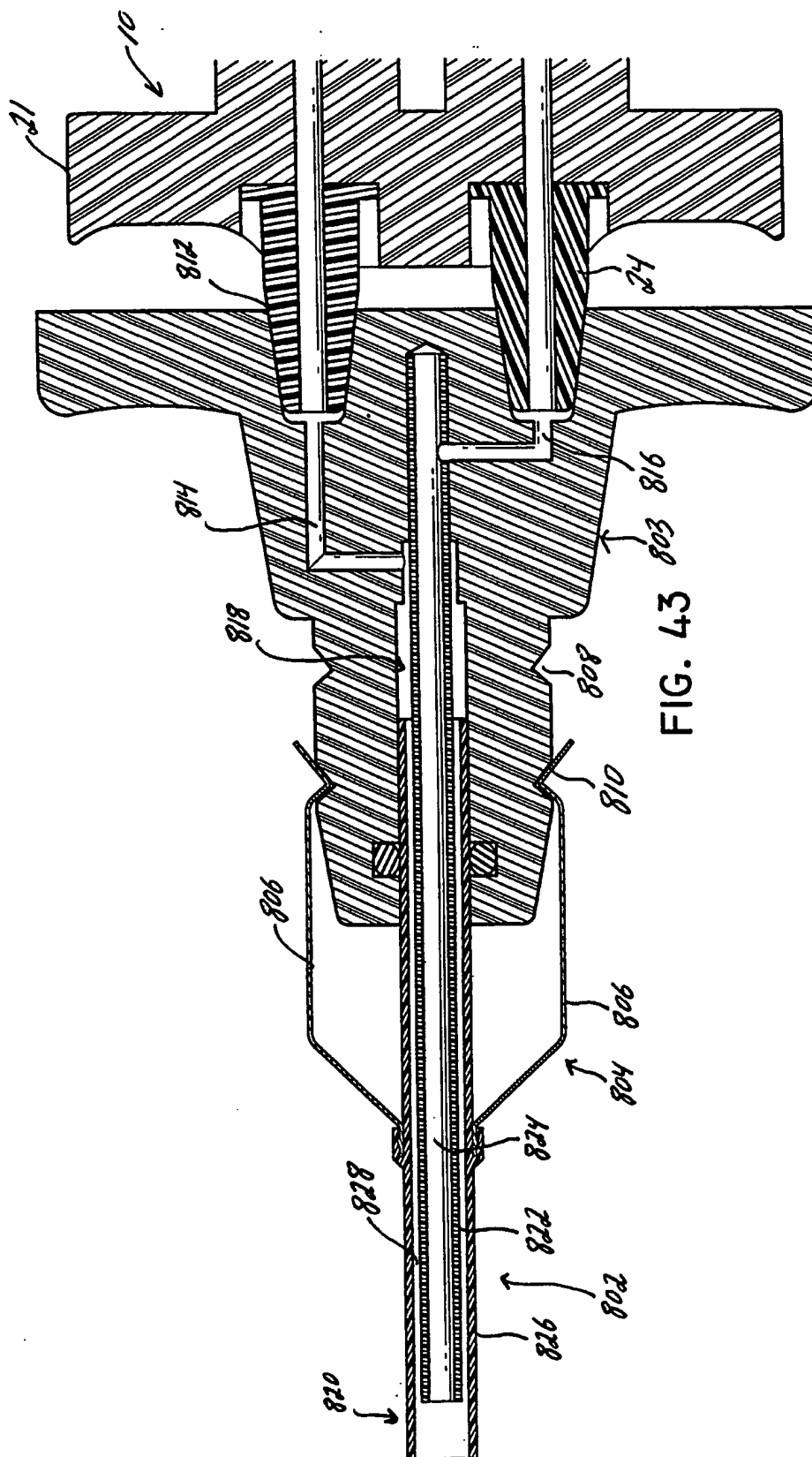
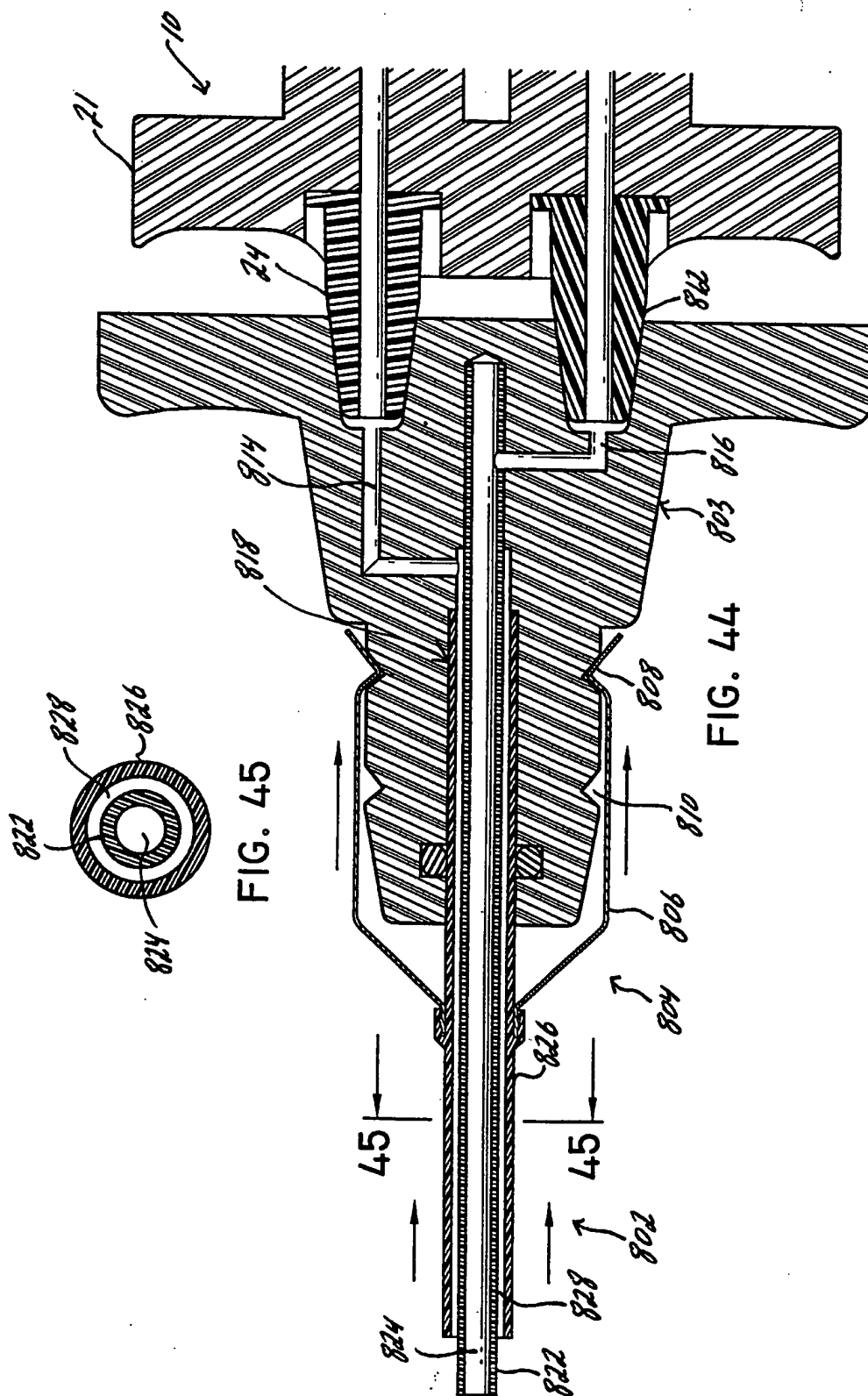


FIG. 43



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/19634

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 37/00

US CL :604/82

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 239/303-306, 404, 418 468; 604/88, 94, 187, 191, 218, 310, 311

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,376,079 A (HOLM) 27 December 1994, entire document.	1-38
A	US 5,368,563 A (LONNEMAN et al) 29 November 1994, entire document.	1-38
A, P	US 5,749,968 A (MELANSON et al) 12 May 1998, entire document.	1-38



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

16 DECEMBER 1998

Date of mailing of the international search report

21 JAN 1999

Name and mailing address of the ISA/US
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Washington, D.C. 20231

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